Proceedings and Recommendations of the

FIRST ROUND TABLE CONFERENCE ON

PREVENTION OF HIV TRANSMISSION FROM MOTHERS TO INFANTS

- Strategies for India

organised by

Department of Experimental Medicine & AIDS Resource Center

The T. N. Dr. M.G.R. Medical University,
Chennai - 600 032

Chennai (Madras) INDIA
Nov 6 and 7, 1998

Co - Sponsors
UNICEF
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ELIZABETH GLASER PAEDIATRIC AIDS FOUNDATION, USA

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STOP PRESS

As the 2nd impression of this Proceedings and Recommendations of the First Round Table Conference goes to press we are happy to inform our readers that the National AIDS Control Organisation (NACO) has initiated a "feasibility study of administering short term AZT intrevention among HIV infected mothers to prevent mother to child transmission of HIV in India". This joint collaborative project is funded by the National AIDS Control Organisation, New Delhi and the UNICEF, India. The principal investigator at the NACO is Dr.P.L.Joshi, Joint Director (Technical) NACO, New Delhi. This study will be implemented in 11 centers throughout India. NARI, Pune and the Department of Experimental Medicine of Tamil Nadu Dr. MGR Medical University will provide training and laboratory support for this programme. We sincerely wish that this initiative will pave way for developing an "Indian Program" that will eventually become part of the Public health policy in India and in the neighbouring countries.

Dr. N.M.SAMUEL
Editor

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FOREWORD

It gives me great pleasure to be able to present you with this publication of the Proceedings and Recommendations of the first Round Table Conference - Prevention of HIV Transmission from Mothers to Infants - Strategies tor India held in Chennai on November 6th and 7th. 1998.

I express my thanks to the co-sponsors of the conference - UNICEF, Glaxo Wellcome and the Elizabeth Glaser Foundation, USA for their support. We believe that education and training of the medical community has a vital relevance in prevention and control of HIV in the community. I am confident that the Recommendations of the conference, if implemented (even partially), will bring positive contribution in the reduction of MTCT in our country.

I would like to pay my tribute to Dr. (Major) D. Raja (former Vice-Chancellor) under whose Presidentship this conference was held, who shouldered the responsibility of conducting this conference and to the staff of the Department of Experimental Medicine for organising this unique conference.

I sincerely hope that the contents of the publication will be of some use for anyone concerned in MTCT and Paediatric AIDS.

Dr. K. Anandakannan
Vice-Chancellor
Tamil Nadu Dr. MGR Medical University
Guindy, Chennai 600 032

INTRODUCTION

The Department of Experimental Medicine and AIDS Resource Cefntre, TN Dr. MGR Medical University was highly honoured to host the first Round Table Conference on Prevention of HIV Transmission from Mothers to Infants - Strategies for India, which was held in Chennai (Madras) on November 9th and 10th 1998.

The objectives of the workshop were:

- To acquaint the participants about the efficacy of administering Zidovudine during pregnancy. The use of Zidovudine during pregnancy reduces the risk of mother to child transmission (MTCT) of HIV by 66%, according to the ACTG 076 regimen.However, unless the ACTG 076 regimen is suitably modified, it will be out of reach for countries like India, where there are over 90% incidence of HIV infection. Women in these countries seek prenatal - care usually after the 28th week of pregnancy. They may also seek assistance at the time of delivery. Hence, short course anti-viral regimens that are cheap and easy to implement are needed. The Thai regimen was just the right answer. By using a much shorter oral course during pregnancy with no infant dose, this regime reduced MTCT by 50%. All mothers in this study did not breast-feed their infants.

- To strengthen the National AIDS Control training programmes through international co-operation.

- To consider the establishment of an international HIV/AIDS Training and Resource Centre in the University.

The 110 delegates and observers came from all parts of India, USA, Australia, France and the UK, as well as representatives from several organisations involved in HIV/AIDS control programmes. They were paediatricians, obstetricians, planners, laboratory scientists, physicians, field workers, administrators, Vice-Chancellors and Directors of Medical Education. It is gratifying to note the spirit of partnership and the harmonious atmosphere which prevailed throughout the discussions and exchange of information among the participants.

It is my conviction that the Round Table Conference was only the beginning of the tremendous task lying ahead of us, i.e. the training of healthcare workers and integration of HIV/AIDS preventive activities into general healthcare services.

The purpose of publishing the Proceedings of this conference is to inform those who were not able to participate in this unique conference, that short course Zidovudine will reduce MTCT of HIV; and to provide the participants with an aide-memoire as they seek to apply the lessons learned in this conference to their own programmes.

I would like to take this opportunity to express my gratitude to my overseas friends Dr. Arthur Ammann, Mrs. Marilyn Ammann, Dr.Wendy Holmes, Dr. Koen Rompay, Wafei Fawzi and Dr. Elizabeth Dax without whose assistance the conference would not have been possible. I wish to extend my sincere appreciation to the Government of Tamil Nadu, the TN Dr. MGR Medical University, UNICEF, Glaxo Wellcome, the Elizabeth Glaser Foundation and to all the participants for their valuable contribution to the conference.

Dr.N.M. Samuel
Professor & Head
Department of Experimental Medicine & AIDS Resource Centre
Organising Secretary
Tamil Nadu Dr. MGR Medical University

WHY THE ROUND TABLE CONFERENCE?

The World Health Organisation estimates that there are approximately 1600 children infected with HIV everyday. Nearly 600,000 new infections occur every year among children throughout the world, of which 90% occur in the developing countries. Two drug trials using AZT in USA and Thailand have shown the reduction in transmission from 70% and 50% respectively.

The three part AZT regimen was modified in Mumbai and Chennai. Even though small, the relevance of these observational studies is unquestionable. As the number of HIV infections in infants is increasing in India, there is an urgent need for an effective and affordable intervention to prevent perinatal transmission of HIV. The relevance of these observational studies, even though small, is unquestionable. Effective and affordable intervention to prevent perinatal transmission in India is the urgent need as the number of HIV infections in infants is increasing. Before embarking on clinical trials in India, it is necessary to review both the ACTG076 trials and the short course Thai trial in addition to other non-anti retroviral strategies impassionately.

The issues that need to be addressed are:

- Should breast-feeding be promoted and supported in India in the context of the HIV epidemic?
- What are the ethical issues relating to informed consent and how to ensure counselling and testing of registered and unregistered mothers.
- What type of scientific paradigm should be adopted in this research study to adhere to the fundamental ethical principles?
- If an intervention proves to be safe and effective will it then be provided to all in India as part of public health policy?

These issues call for extensive discussions which must include the voices of all concerned to reduce the burden of perinatal transmission of HIV in India.

We are confident that your presence at the conference will contribute to the success of this undertaking.

INAUGURAL CEREMONY

WELCOME ADDRESS

Mr. J.P. Rajapandian
Registrar, Tamil Nadu Dr. MGR Medical University

Respected Vice-Chancellor of our Medical University, respected Secretary to the Government, Health and Family Welfare Department, other dignitaries on the dais and the participants.

It is with great pleasure that I welcome each one of you for this Conference. I especially welcome the Secretary to the Government, Health and Family Welfare Department, Dr. Sunderadevaṅ, who has honoured us with his eminent presence in spite of his pressing official work. It is our privilege to welcome Dr. Arthur Ammann who is the President, Global Strategies for HIV Prevention. It is also a privilege to have him with us at this Conference as the Chairperson. I welcome the Director of Medical Education Dr. Jayachandran and the Director of Medical Education of the Government of Kerala, Dr. Uma Dethan. I also welcome Mr. Khusrokhan who is the Managing Director of the Glaxo Wellcome, India, and Ms. Isabel Austin, who is the UNICEF representative for Tamil Nadu and Kerala. Glaxo Wellcome and the UNICEF are the co-sponsors, along with the Elizabeth Glaser Foundation of USA, for this Conference. A warm welcome to the medical personalities of Chennai city, other Officers of the Tamil Nadu Dr. MGR Medical University and other participants from various states of India. This unique Conference is conducted by the Department of Experimental Medicine under the leadership of Dr. N.M. Samuel of the Tamil Nadu Dr. MGR Medical University. This Conference is a unique one as it is the first of its kind in India. I welcome one and all and wish this Conference a grand success.

WELCOME ADDRESS

Dr. Arthur Ammann
Conference Chair

Prevention of HIV infection must be made a priority for India. Delays in implementation of known effective strategies can be costly. An antibody test for HIV was made available worldwide in 1985. Many countries acknowledged that HIV transmission by blood transfusion could be prevented and instituted universal testing of all blood products to prevent this mode of transmission. A two-year delay in blood testing policy in India is estimated to have resulted in 350,000 new infections.

Since 1994 we have known that AZT given to HIV infected mothers during pregnancy, beginning at the 14th week of gestation, and to the infant for six weeks in the absence of breast-feeding, can reduce HIV transmission by 60%. As the diagnosis of HIV infection is made sooner and as the treatment has improved, perinatal HIV transmission rates have dropped to less than 2% in some developed countries. More recent studies have shown that a 50% reduction in perinatal transmission can be achieved with as few as four weeks of AZT treatment. While these international studies document that shorter and less expensive treatment are effective, they fail to address many of the issues in countries such as India, where many women receive first medical care at the time of labour and delivery and where there is no option other than to breast-feed. Lest we become discouraged, however, it has been recently shown than even very short courses of AZT may decrease HIV transmission: perhaps not to the degree as the full course, but nevertheless, a significant decrease.

India has approximately 20 million births per year with an estimated 1% to 2% HIV seroprevalence in pregnant women. This would mean that 200,000 to 400,000 HIV infected women deliver each year with 80,000 to 160,000 infants becoming infected. This is 400 to 800 times the number of infected infants born in US each year, numbers which cannot be ignored.

Much can be done to prevent perinatal HIV infection even when resources are limited. Studies have documented the success of counselling and testing prior to pregnancy, encouraging a delay in first sexual intercourse, use of condoms and mutual monogamy. Prenatal counselling and HIV testing are equally critical and

must involve both the sexual partners. If a pregnant women is HIV positive, then other options are available including treatment of STDs, nutritional supplementation, elective Caesarian section, AZT, other anti-retroviral therapy, counselling concerning breast-feeding and counselling regarding future pregnancies. It is my belief that to effect major changes in the control of the HIV/AIDS epidemic, the community must first respond and develop their own individual programs. To wait for a national government response is to accept the state of denial that appears to be ubiquitous among political leaders. This conference will discuss what can be done now and will conclude with specific recommendations regarding effective strategies, some of which can be implemented now. and some which can be used to effect change in other communities, regions, states and eventually at the national level.

The predictions for the progression of the epidemic in India are ominous. In one year, the number has gone up from 7 million to 10 million. While they remain numbers for many, for those of you who work among the infected, they are people with faces - women, children, mothers, fathers, brothers, sisters, husbands and wives. In too many instances we have seen a diagnosis of HIV infection open the door to discrimination, ostracism, neglect, abandonment and abuse, especially for women and children. We must provide the opportunity to these victims to enter a new door- one of compassion, health-care and acceptance. We must bring about a change, in our attitude and through the example of our communities, bring pressure to bear on our political leaders to act responsibly. And we must explore every avenue that will bring about HIV prevention and eliminate discrimination. We require sustained research, implementation of programs, improved access to healthcare, legal measures and economic and legislative approaches. Only when we effect change can we be satisfied that progress has occurred.

PRESIDENTIAL ADDRESS

Dr. (Major) D. Raja
Vice-Chancellor, Tamil Nadu Dr.MGR Medical University.

Our respected Secretary of Health to the Government of Tamil Nadu , Dr. Sunderadevan, Dr. Arthur Ammann, President of Global Strategies for Prevention of HIV, Director o f Medical Education of Tamil Nadu, Dr. Jeyachandran, Director of Medical Education Kerala - Dr. Uma Dethan, Mr. Khushrokhan, Ms. Isabel Austin and the Registrar of our University, Mr. Rajapandian, distinguished guests, friends, ladies and gentlemen and friends from the Press.

At the outset, I am very happy to be here because the Department of Experimental Medicine of the Tamil Nadu Dr. MGR Medical University is conducting the Round Table Conference on Prevention of HIV Transmission from Mothers to Infants - Strategies for India. After successfully conducting the First International Conference on AIDS India 2000 last year, we are conducting this Round Table Conference as a sequel because we have to detect and reduce the prevalence of paediatric infection. As you know, a disease which was virtually unknown before 1981, has taken such a toll throughout the world. It was detected in our country in the year 1987. Unfortunately, the first few cases were detected in Madras City, and from that day onwards, the entire nation has been fighting the disease on a war footing. The government of Tamil Nadu has taken extreme care as the fight against AIDS is concerned.

In 1994, the firs effective intervention to reduce the perinatal transmission of HIV was developed in USA in ACTG 076 study. In that trial, Zidovudine was given orally to HIV positive pregnant women as early as the second trimester of pregnancy, intravenously during labour and orally to their newborns, for 6 weeks This reduced the incidence of HIV infection by two thirds-from 25% to 8%

Since then, the Department of Experimental Medicine (DEM) in our University has started to screen pregnant women for HIV infection with the main objective of offering AZT. The modified ACTG 076 was given to pregnant women of our country and their new born infants.

Even though the numbers were small, the study has been worthwhile. Many issues were encountered eg. breast-feeding, counselling of partners, and parents, includ-

ing members of the joint family etc. The findings were published in the National Medical Journal in 1996.

Since 1993, our university has given a fillip to HIV/ AIDS awareness and training. A book on AIDS was published both in English and Tamil. Several training programmes were conducted in the city and in the district headquarters of Tamil Nadu.

The acquisition of a microearth V-satellite station to access and download MEDLARS database, along with AIDSLINE from the National Library of USA is a noteworthy achievement . This has benefitted medical students and faculty members as they can obtain the latest information on HIV/ AIDS and its management. Diagnostic services and research on traditional drugs, along with anti-retrovirals are being undertaken. These efforts were presented at the recently held AIDS International Conference in Geneva.

The first International Conference on AIDS India 2000 was organised a year ago when it attracted 550 participants from the whole of India and the neighbouring countries. Seventeen foreign experts shared their experiences with the Indian community working with HIV/AIDS.

The Department of Experimental Medicine (DEM) had organised a Round Table Conference in July 1995 to arrive at a consensus on the definition and staging of HIV/AIDS, since there was no acceptable Indian classification of HIV/AIDS.

Today's Round Table Conference is yet another valuable contribution in the fight against HIV/AIDS, jointly sponsored by UNICEF, Glaxo Wellcome and the Elizabeth Glaser Foundation. The university firmly believes that its role is to impart knowledge in the current advances in medicine to the health care community. The academia needs to be involved in the prevention and control of infectious diseases such as HIV/AIDS as they have a positive impact on the community. The University, with its special status as an autonomous and non-governmental body, can supplement the efforts of the government. It is the medical community, along with bio-medical workers, who will ultimately be instrumental in controlling and eradicating HIV/AIDS from the earth.

I am happy to see obstetricians and paediatricians representing every medical school in Tamil Nadu and Kerala participating in this conference. We are fortunate to have Dr. Uma Dethan, DME of Kerala and Dr. Jeyachandran, DME from

Tamil Nadu, participating in this Round Table Conference. With their good offices, this topic can be studied, researched and incorporated in the medical curriculum of UG/PG students.

We live in a global village and our lives are inter-connected whether we are professional or executives from the industry. We cannot live in isolation. We are happy that Glaxo Wellcome is joining our efforts in the fight against HIV/AIDS. They have several drugs for the treatment of HIV/AIDS. We solicit their support for our studies. Glaxo Wellcome is known as a multinational firm "with a heart". I sincerely hope that their presence here today is the beginning of a fruitful relationship in the fight against HIV/AIDS.

A word of gratitude to all overseas experts who have travelled long distances to share their experiences with us here in Chennai. Thank you.

Several Indian experts have come from Manipur, Calcutta, Delhi, Vellore, Ahmedahad and Mumbai. Thank you for your concern in the battle against HIV/AIDS.

Let each one of us present here this morning pledge that we will use the available preventive strategies in our practice and teaching to reduce perinatal HIV transmission.

Thank You.

INAUGURAL ADDRESS

Dr. N. Sundaradevan
Secretary of Health and Family Welfare Department, Govt of Tamil Nadu

Ladies and Gentlemen,

I am happy to be here to inaugurate the Round Table Conference on Prevention of HIV Transmission from Mothers to Infants - Strategies for India, organised by the Department of Experimental Medicine of the Tamil Nadu Dr. MGR Medical University. I thank the organisers for this opportunity. We are aware that there are critics who question the importance and prominence given to HIV/AIDS and the high visibility and publicity campaigns for HIV/AIDS over other diseases. Some of these critics genuinely feel that HIV/AIDS has stolen a march over more lethal diseases such as tuberculosis. All of us are aware that even today globally, the number of persons dying of tuberculosis is higher than the number of persons dying due to HIV/AIDS. Does it mean the critics are right? The answer to this question lies not in numbers but in nature of this disease. Unlike most other diseases, there is a long incubation period between infection and the appearance of the symptoms of the disease, namely the first opportunistic infection in the case of HIV/AIDS. Thus an individual may be blissfully unaware of the fact that he has been infected. He may lead a normal and healthy life for several years after infection but he may be infecting scores of others, knowingly or unknowingly, during this period. For most other infections there is a preventive immunisation or a cure but not for HIV/AIDS as yet. In the case of AIDS, death is preceded by a fairly long period of illness, almost like many chronic diseases, and its extended treatment costs the individual and society dearly. The treatment for the opportunistic infections as well as care during full-blown AIDS is extremely expensive for a country like India. HIV/AIDS primarily affects adults in their economically productive years. There is high likelihood of multiple transferring infection to the child if there is no prevention. If our infection rate among the general public is one percent, you can imagine the number of infected children born in this state and the country. As you know there are about 1.2 million births in Tamil Nadu every year. If one percent of the mothers are infected and 30 percent of them vertically transmit the infection, there will be 3600 children born every year in Tamil Nadu alone with HIV infection. It is high time that we devise strategies for preventing HIV infec-

tion. It is in this background that today's Round Table Conference assumes special significance. If the distinguished gathering here can throw up useful suggestions and draw useful strategies to combat the threat of vertical transmission of HIV infection from mothers to children, we would be doing yeomen service to this society. I congratulate the MGR Medical University and the Department of Experimental Medicine for having organised this Round Table Conference. I formally inaugurate the conference and wish all the participants a useful day ahead.

Thank You.

tiatives and for the excellent arrangements. Since I am the last one to speak to you today, you will now have the occasion to interact in smaller groups in focusing on various aspects of these issues with resource persons, with people coming from different places and with participants with different perspectives. I want to congratulate the organisers who adopted this methodology which will be extremely productive. We are convinced that this conference will contribute to the development of guidelines for various research projects which are currently going on, especially in Tamil Nadu, and prepare the participants for another global event in Canada during the year 1999 - Strategies for the Prevention of HIV Transmission.

The timing of this conference is an advantage for India because both local and global issues in tackling the problem of HIV/AIDS will be thrashed out. India will therefore be in an extremely strong and well prepared position to contribute fruitfully in a global discussion on HIV. The national experience in controlling HIV/AIDS, as well as mother to child transmission, will be widely appreciated in a global context. We wish you a very fruitful discussion and look forward to the outcome of these two days of deliberations.

Thank You.

GREETINGS

Ms. Isabel Austin
UNICEF Representative for Tamil Nadu and Kerala

Respected Health Secretary, Vice-Chancellor of Tamil Nadu Dr. MGR Medical University, DME of Tamil Nadu and Kerala, the President of the American AIDS Foundation, Dr. Arthur Ammann, Mr. Khusrokhan, Managing Director of Glaxo Wellcome, resource persons, participants and representatives of research institutes and NGOs.

UNICEF is a partner in the UN joint programme on AIDS, otherwise called UNAIDS. I would like to thank Dr. Sundaradevan who has reminded us of the perspective with which we have to approach this pandemic, as part of the border issue of sexually and non-sexually transmitted diseases which affect women and children everywhere. He has rightly highlighted the specific problems faced by this State and by this country on the mother and child vertical transmission. We all know that the paediatric AIDS is poised to become a major public health problem as is indicated by the fact that the HIV prevalence cases in the antenatal population are increasing and are currently 2 - 2.5% in Mumbai, Chennai, Manipur and Pune. Those of us who have served in Central Africa and have had the occasion to study the pandemic there remember that entire villages were wiped out. AIDS has contributed to the increase in infant mortality rates in some countries in Africa. We are worried that if further progress is not made in the control of the pandemic in India, we might actually face the destruction of the very positive progress that this country has registered in the survival of children in particular. Providing AZT to pregnant women has been shown to reduce the incidence of HIV transmission to infants and is now almost adopted as standard care in the developed countries. What is needed in India and other developing countries is the standardisation of effective and affordable interventions to prevent perinatal transmission. While most cases of vertical transmission of HIV occurs during late pregnancy and delivery, more than one third of these infected infants are infected through breast-feeding. This, for us in the United Nations, has been a serious ethical question. Policies regarding HIV and infant-feeding need to consider the several elements that have been listed by joint United Nations programmes on HIV and AIDS, which I will now share with you. These joint unit statements on HIV and infant feeding recommends that as a general principle in all populations, irre-

spective of HIV infection rates, breast-feeding should continue to be protected, supported and promoted keeping in view the much greater risk of artificial feeding to the survival of infants. Access to voluntary and confidential HIV counselling and testing should be facilitated for women and men of reproductive age, providing the best available information on the benefits of breast-feeding and risk of transmission of HIV through breast-feeding, and the possible advantage associated with other methods of infant feeding, ensuring thereby informed choices. Another issue that we in UNICEF would like you to look at is not to isolate the issue of mother to child transmission from the broader issue of the HIV/AIDS pandemic. I am grateful and want to felicitate the speakers before me who have referred to those broad issues in terms of ethics of care of AIDS patients in terms of social and economic consequences of the epidemic in this country, in terms of the reproductive health of women in this country. We strongly feel that women empowerment has to do also with the strategy that you have to evolve during the coming two days. We feel that the status of women in society should be improved so that the vulnerability of HIV infection is reduced. The speakers have referred to the studies conducted in Kerala and Tamil Nadu on the prevalence of sexually transmitted diseases. We would like to recommend that the target group be provided with social support not only to make informed decisions, but also to carry them out with least risk to themselves and children. Let us remember, as the Health Secretary has rightly pointed out, that about half of the newly infected people each year in the developing world might be women and children. We want to thank our partner in this event, Glaxo Wellcome, who are involved in the production and distribution of products which are widely used in the control and cure of this disease, who came forward willingly in India. We want to call on other manufacturers and distributors of products that fall within the code of marketing of breast milk substitutes not to take advantage of the issue of mother to child transmission and evade their responsibilities. They should continue to take the necessary action to ensure that their conduct at every level conforms to the principle and aims of the code on marketing breast milk substitutes. We at UNICEF are conscious that while the pandemic is affecting the whole of India, a few states seem to have a higher risk than others. Tamil Nadu, Maharashtra, Manipur and Gujarat are those states, and we want to thank those participants who have come from these states to actively participate in the discussions. In closing, I would like to felicitate this University, the Department of Experimental Medicine, and especially Dr. Samuel and all the members of the organising committee for their ini-

GREETINGS

Dr. Uma Dethan
Director of Medical Education, Kerala

Respected Health Secretary of Tamil Nadu, Shri Sundaradevan, respected Vice-Chancellor of the Tamil Nadu Dr. MGR Medical University, Shri Dr. (Major) D. Raja, Dr. Arthur Ammann, Mr. Khusrokhan, Ms. Isabel Austin, Mr. Rajapandian, my counterpart Prof. Jeyachandran, Dr. Samuel, distinguished professors, resource persons, delegates and members of the faculty of Experimental Medicine.

At the outset I express my sincere thanks to the respected Vice-Chancellor and the University for extending an invitation to the delegates from the sister state of Kerala. We, the health administrators of Kerala, boast very often that Kerala is the only state that has achieved most of the health indices we ought to have achieved by the year 2000. But we have one deficiency. We are envious of the State of Tamil Nadu for having an excellent Medical University and a dynamic Vice-Chancellor. I am sure that you will agree with me if I say that the Department of Experimental Medicine is one of its kind in the whole country doing a wonderful job. The best example is the hosting of this Round Table Conference and that too with delegates from abroad. HIV/AIDS is rightly called the disease of the century. When the disease was diagnosed 15 to 16 years ago in the US, we were not bothered about it. We thought that it was an infection confined to the West. But slowly we are now responding because in a developing country like India with poor resources, it will be difficult to plan effective interventions. Unfortunately we do not even have proper epidemiological date. NACO is giving out certain figures. Local blood banks and other organisations give different figures. Recently in Kerala, we conducted a survey with the help of the London School of Hygiene and Tropical Medicine - the situational analysis of sexual health in India. They did two surveys one in Gujarat and one in Trivandrum. The results were really astonishing. We never thought that a city like Trivandrum would have such a high prevalence of STDs. Not only AIDS, but another threat facing us is the Hepatitis B infection. The University is convening this conference on a very important topic of contemporary importance i.e. the transmission of HIV from mothers to infants. It is estimated that this is one of the forms of transmission of the disease. We are trying to reduce the other methods of transmission by implementing safe blood transfusion and using disposable syringes and other precautions. We need to

plan correct intervention strategies to reduce transmission from mothers to infants. We know that in the State of Kerala, 97% of deliveries take place in hospitals. This is not so in other states. When we plan strategies, we must also take into account the cost effectiveness of the programme. Fortunately we have among us very good resources persons and I am sure that the deliberations of this Conference will be of help to the health personnel of this state as well as the state of Kerala and India in general. Once again, I congratulate the organisers for arranging the conference in an excellent manner and I wish it all success.

Thank You.

GREETINGS

Mr. H. Khushrokhan
Managing Director, Glaxo Wellcome (India)

Honourable Vice-Chancellor, Dr. (Major) D. Raja, Health Secretary Dr. N. Sundaradevan, Dr. Arthur Ammann, Dr. Uma Dethan, Ms. Isabel Austin, Dr. Samuel, doctors, and respected guests.

I am delighted that we at Glaxo Wellcome have had an opportunity to be associated with something as important and significant as the AIDS problem in India at this workshop. In my opinion, and I am a lay person, the AIDS problem is reaching frightening proportions in India, and I do not want to look just at numbers. I think there is a deeper problem here and a huge social problem as well for the country and it is frightening to think about the opportunistic infections which can arise in AIDS patients. These are drug resistant infections and these can create a series of new medical problems which we know nothing about today. Whatever we can do in a small way, by working together, is going to be very valuable in the years ahead. This is really an important subject because we are trying to stop vertical transmission of AIDS. And if we can do something in this area, it is well worth the effort. On a rough estimate, about 600,000 newborns are infected with HIV/AIDS every year. Considering our large population and our alarming growth rate of 2% per annum, it is not very difficult to calculate that a significant proportion of these children will come from India. As Dr. Samuel pointed out, 50% of HIV infected newborns could be born in our country if this problem is not addressed quickly. There are several constituents working on this problem, and we, being a pharmaceutical company actively involved in AIDS, would like to be one of the constituents. We have been in the field of research of antiviral drugs for several years now, starting with the invention of Zidovudine by Borroughs Wellcome, followed by bringing Lamivudine into the market. The combination product, Combivir, has certainly helped with compliance of therapy. A new protease inhibitor, Abacavir (a new NRTI), as well as many existing drugs in AIDS management, are in the pipeline of New Product releases. We have a new generation of NNRTI under development at the moment and we have now captive technology for DNA vaccination - the powder jet technology - that could bring new discoveries in this

field. In addition, Glaxo Wellcome has a wealth of clinical data on HIV, having been in this field for so long.

Therefore we would be a valuable source of information and data in this area. We offer ourselves to work in partnership with the government, doctors, NGOs and organisations tackling this world problem. We feel that if everybody is committed to this, a lot can be achieved. I think the topic today has several issues attached to it. I think we are concerned with evolving a simple treatment regimen. We need simplicity and cost effectiveness. We need compliance and we have to address the social problems of this disease. This is not an easy issue to tackle. It is like Sophie's choice, whom do we save? I think we have to think on saving lives of children. As a company, we are committed to fighting the disease worldwide and this is certainly one of our main thrust areas. Generally we would like to be seen not as a provider of medicine to the community but as contributors to health care.

VOTE OF THANKS

Dr. N.M. Samuel
Professor and Head, Department of Experimental Medicine
Organising Secretary

Our revered Vice-Chancellor Dr. (Major) D. Raja, Dr. Sundaradevan, our Secretary of Health and Family Welfare, Dr. Jeyachandran, our Director of Medical Education, Dr. Uma Dethan, Director of Medical Education from Kerala, Dr. Arthur Ammann, the Chairperson of the Conference, Mr. Khushrokhan, the Managing Director of Glaxo Wellcome, Madam Isabel Austin, ladies and gentlemen.

I am happy to see you here this morning. It is good that you have accepted our invitation and some of you have travelled long distances to be with us. This conference would not have been possible if not for the guidance we have received from our Vice-Chancellor and our Registrar. Whenever we go to them with our problems, especially to our Vice-Chancellor, he always comes out and supports us and sits with us and plans each item in detail. And so this morning I want to thank you whole-heartedly for your support for our research activities. And to you, Dr. Uma Dethan, for coming and bringing your team of obstetricians and paediatricians from your medical colleges in Kerala. Dr. Sundaradevan is the Secretary of Health and a very important person in the Ministry of Health here in Tamil Nadu. He is also the President of the Tamil Nadu State AIDS Control Society. Dr. Jeyachandran, our DME, we thank you sir; Mr. Khushrokhan, the Managing Director of Glaxo Wellcome thank you for your support and co-operation and for the team you have brought from Mumbai for this Conference. Thank you, Madam Isabel Austin and Dr. Srilatha of UNICEF, for agreeing to co-sponsor this conference. We have a co-sponsor who is not present here, that is the Elizabeth Glaser Foundation, and we request Dr. Ammann, on our behalf to kindly thank Catherine and Trish who supported us in bringing the overseas participants for this Conference. Dr. Ammann, who is an internationally acclaimed HIV/AIDS specialist, noted the world's first cases of vertical transmission and we are very fortunate to have him and his wife this morning with us and we thank him. We thank overseas experts who have come from the USA- Drs. Koen, Fawzi and Savitha Pahwa who had a mild heart attack in Delhi, we are very sorry to hear the news.

GREETINGS

Dr. C.S. Jeyachandran
Director of Medical Education, Tamil Nadu

Respected Secretary of Health and Family Welfare Department, Vice-Chancellor of Tamil Nadu Dr. MGR Medical University, President of the American AIDS Foundation for AIDS Research, Dr. Arthur Ammann, DME of Kerala Dr. Uma Dethan, Organising Secretary Dr. Samuel and other distinguished guests.

I am happy to participate in the Round Table Conference on Prevention of HIV Transmission from Mothers to Infants - Strategies for India. It is the need of the hour to have conferences like this, at a time when there are reports that India will top the list of HIV/AIDS patients very soon. Even after many years of research, medicines to cure AIDS is elusive, and at present, we have to resort only to preventive measures. Our high illiteracy rate and over population add to fuel to the burning problems of AIDS.

Dr. Dorothy Bray from the UK, Dr. Wendy Holmes and Dr. Dax from Australia, we thank you for coming. I thank the national experts who are here and all the participants for their support.

WORKING PAPERS

I. PATHOGENESIS AND PREVENTION OF PERINATAL HIV TRANSMISSION

Dr. Arthur Ammann
President, Global Strategies for HIV Prevention, San Rafael, California, USA

I have selected certain aspects of perinatal transmission to emphasise and discuss rather than try to go through a broad issue on pathogenesis. Fundamentally, one very important thing for all of us to realise from the international community is that we are currently facing a situation where we have made an enormous investment in research. My estimates are that investing in HIV/AIDS in infants and children are probably somewhere around a billion US dollars in trying to find some of the answers. The point is that we have found some of the answers and now we need to move forward in particular, in implementing some of the answers that we have obtained. When we talk about preventing perinatal transmission we are primarily talking about a pharmacological approach. A term that I used a few years ago was pharmacological vaccine. We now have a large number of drugs that are used to treat the virus. But we still have out of this entire list only one drug, AZT, that is approved to be used in pregnancy which has been documented and proven to prevent HIV transmission. This is an incredible observation when you think about it. When AZT was first approved in 1987, it was hailed as an important treatment, it still is the mainstay in the treatment, but now in combination with other therapies. It is not a very potent drug compared to some of the new drugs. It changed the mortality rates, the opportunistic infection rates, and it changed the progression to AIDS. But there were many problems. Until other drugs became available and were approved, especially the protease inhibitors, the real dramatic changes in the progression of the disease were not observed.

It is clear to me in terms of international conferences, in terms of focus and in terms of expenditure of funds that there is insufficient attention being given to the prevention strategies. Even in this particular aspect we see that of the 11 drugs approved since 1987 for use in adults - ddi approved in adults and children, ddC still only for the adults - only d4T has been recently approved for children. When I say children, it does not mean infants. We still do not have approval for many of these drugs for infants. As for the protease inhibitors, only recently has Ritanovir been approved. Nelfinavir has been approved simultaneously for adults and chil-

dren. Out of these 11 drugs and probably another 10 new anti-retroviral agents in the next year and a half, we still have only one drug that has been approved for use in pregnant women. And there is only one drug where we have sufficient data to say that the drug is safe and the drug is effective in preventing HIV transmission. In spite of this, the current recommendation and standard of care in Europe and US in that if a mother has HIV infection and she is put on treatment with combination, then that combination therapy should be continued throughout pregnancy. And that mother is advised that there is inadequate safety data to determine whether or not that combination therapy is safe for the foetus during pregnancy. Is the combination therapy more effective in preventing HIV transmission than AZT alone? That is the most important question for us to address here at this particular conference. My personal feeling is with what we are seeing with AZT alone is really seeing a much more dramatic effect that we ever anticipated even after the February 1994 results. For example in the United States, the transmitted virus has steadily decreased even though many of the mothers still remained in the AZT mono-therapy. Many of you are aware of the report at the Geneva meeting from the European group, that when AZT was given to pregnant women in the 076 regimen, coupled with caesarian section and no breast-feeding -something that cannot be done in the developing countries, the transmission decreased to less than 1%. That is much more than we ever anticipated from a vaccine or the combination therapy. So what does it tell us about the pathogenesis of HIV infection? I think we are seeing a preventive effect that is beyond the effect of the virus on restoration of the immune system in the mother and reduction of the viral load. Hence there must be something else coupled with AZT that is causing this reduction in prevention. My personal feeling is that there is the other factor that we must emphasize in this meeting and that is the integration of health care services so that we are able to provide better prenatal care for the mother, because what is really happening in the US is that we are now seeing a much more aggressive posture towards HIV counselling and testing. Mothers are being diagnosed early. They are often being diagnosed before they become pregnant or early in pregnancy. They are being offered other diagnostic tests such as diagnosis of sexually transmitted diseases. We are paying attention to nutrition and other fundamental aspects that should be a part of all routine prenatal care. It is being incorporated into prenatal care. Therefore, even without the AZT, as shown in one of the US studies, there is an initial reduction of transmission of HIV before AZT was even used. That does not mean that we should not use AZT. What we are seeing

is a synergy between improved health care and AZT. I feel that we really need to look at some other drugs for perinatal transmission in combination. I am not sure that they are absolutely needed unless we get into a problem of resistance to AZT.

Now what other drugs should we be looking at? What kind of backup should we have out of this list? I think protease inhibitors represent a real problem for developing countries since they are enormously expensive and difficult to produce. It will be very hard to get the cost of those drugs down. But there are some other drugs that actually may become attractive as time goes on. On of these is Nevaripine, and this drug has a unique 'niche' in terms of treatment. Resistance develops very rapidly to Nevaripine, usually within 4-8 weeks after starting therapy, as mono-therapy. But its attractiveness is in the fact that it is very potent, it can be used for short periods of times, it has a long half-life. It has been shown in some of the studies in Uganda that it gets excreted in breast milk, and it comes across the placenta in very high levels. Hence it may be an attractive drug to be used in late pregnancy as mono-therapy, in developing countries. Because of its long duration of action in infants, it may be an alternative to AZT. This then is one of the research questions that we have. We will hear later in this Conference from Dr. Koen Rompay who will be talking about another drug that has not been approved in infants or women. That is PMPA, and you will hear why that is attractive in the future. But as I look at this list of drugs and the drugs that are coming down the pipeline as we say, we still realize that we haven't had a very effective compound that can be used by itself or in combination. We will hear about the 3TC combination for use in pregnancy. We really have to use what is available to prevent transmission.

As I travel in the international community I feel that we are coming under more criticism for emphasizing perinatal transmission, because we are selecting a particular population to treat, that is, women and children. We are being accused of ignoring the other problems. But I want to point out that we really have to emphasize on this area of prevention, because the international community and the world cannot afford to continue to emphasize on the treatment only without really increasing its emphasis on prevention. This is really an economic argument. We know the figures; we know that this is a very costly epidemic in terms of future generations of the children. We are going to lose an entire generation of children. Let us go into some of the reasons why this is important from an economic point of view. We know recently there was an announcement from the South African

Health Minister that the South African Government has decided not to provide AZT for HIV infected pregnant women. And the reason given was because it was not cost effective. And that is absolutely incorrect. It is one of the most cost-effective treatments available in terms of reducing perinatal transmission. If we are able to provide AZT and to prevent 50% of the infections worldwide and calculate the cost of AZT, that's about $100 per infected mother. In this case, assuming breast-feeding, we can see the cost of this kind of program worldwide to be about $600 million. This does not include other cost factors. If we were not to emphasise prevention, but assume that we have to take care of the individuals who are infected and provide them with combination therapy treatment, the cost over the next 10 years would be $150 billion. This figure is unaffordable. This does not mean that we should not treat with combination therapy, but to consider the overwhelming problems of not emphasizing prevention more than we are doing so at present. It is estimated that there are 30 million infected people in the world. If we want to take 15 million of these infected individuals and treat them with combination therapy plus treat half of the new infections each year with the same therapy, then each year, the cost would eventually be $1.4 trillion. It is clearly not possible without compromising all the other public health programs. And we must get across the impact of the uniqueness of the HIV epidemic, not only in the economic cause, but also the opportunity that HIV/AIDS provides for other microorganisms to multiply and develop resistance and cause other diseases. This is something that we must attack with vigour and I do not think any of us in this conference should be embarrassed or should be on the defensive for saying that this aspect of prevention is very important for us. We must become the advocates for prevention of perinatal transmission.

In terms of counselling and testing who has the right to know? How does one give counselling? Is it on an individual basis because of health care resources? Do you give counselling on a group basis and then individualise it? These are the issues that need to be discussed. The individuals need to be sensitive to the country's specific issues that are present. Keep in mind when we talk about developing treatment protocols for maternal-infant prevention, the cost of treatment that many of us ignore, the surrounding cost of counselling and health care which can be greater than the actual cost of the anti-retroviral treatment. Hence we have a tendency to decrease the cost of antiviral treatment. We also have to have a demand in our public health arenas to obtain the necessary resources for appropriate counselling. Another factor that is being considered in many countries, especially in

the US, is the rapid testing or the same day testing method. Get the results on the same day? Why? Because in many circumstances, when the test is done and there is an interval of days or a week before the result is obtained, it is another visit back to the doctor. This again is something that we should also discuss in terms of implementation. If there is an opportunity to do the test and counsel the individ- ual on the same day, that might be an advantage in many circumstances. And it might also be efficient and economical to provide treatment.

Breast-feeding has already been raised as a very significant issue. This is very difficult. The conference to be held in Montreal will focus attention on this particular topic. It causes a disturbance to what we have been used to regarding the benefits of breast-feeds, and yet we know that there may be as much as 30% increase in the transmission rate because of breast-feeding. But how do we prevent breast-feeding in the developing countries where sterile water is not available, neither the fuel to heat the water to make it sterile? How do we handle the discrimination issue when it is assumed that if a woman does not breast-feed she has HIV infection. And these are the enormous issues which we have to face in an integrated manner in terms of prenatal care so that AIDS does not become a separate issue.

Now we have shorter courses. But shorter courses for the sake of reducing the cost of therapy may not be appropriate. Shorter courses for making therapy easier, making it more available, more convenient and more effective - yes, like longer acting drugs and fewer doses. But I do not think the cost of AZT per se, is the major issue. I think the major issue is how do we provide the overall prenatal care, the treatment of sexually transmitted diseases, adequate nutrition, counselling, administering AZT, and the testing. We talk about research studies. I am little bit uncomfortable at this point with the trend to have shorter and shorter courses until we get to some course that is effective. If we get a short course that reduces transmission by 20%, is that adequate? I do not think so. Our responsibility as physicians and health care workers is not to provide necessarily less and less expensive care. We have to use what is in hand and is available and try to put those resources together.

Here the pharmaceutical company is supporting this meeting. Surely they would like to sell some more of their drugs. They have to survive by having profits. We have to be aware that there is a built-in system of incentives, so they bring to us the drugs. I point out to the people in the US that every single anti-retroviral agent that we have is brought to us by a pharmaceutical company. There needs to

be incentives for them, but we do not want them to charge us too much for the drugs, so we have to work together with them.

Another area that is important is the targeting of the emerging epidemic. At the Geneva meeting, many of you were upset, as I was, on the lack of recognition of India and China Basically India was barely mentioned in the Geneva meeting in terms of the epidemic. And yet you have an enormous number of infections. It will be overwhelming in this country, so we need to pay greater attention to countries that have emerged or emerging epidemic of HIV/AIDS. China is another country, perhaps for the first time, in the history of the epidemic of HIV/AIDS. We can stop an epidemic before it gains large proportions. But here in India the epidemic is mature and we have to pay attention to the problem.

I hope that by tomorrow we could define a successful model of implementation. I don't think we are talking in this meeting about research. There is research within the studies that we are going to be looking at. But I think what we really want to do is to come up with something that is really worthwhile, that will begin the process at the local level and then be extended nationally. And it can be incorporated into your public health system that will help to bring down the number of infected HIV infants. It is not going to be easy and there is going to be a lot of debate about the best way to do it. But to me it is more of implementation than it is research. There are research questions within the implementation. But we are not really trying to devise some new form of treatment on prevention.

The speaker from Thailand is not here, but I want to use this opportunity to highlight the results of a study done there. A comparison with the prevalent practice in the US and Europe in treating HIV cases would not be out of place. As we know, ACTG study is really a two trimester of treatment with AZT, intervenous therapy during pregnancy and treatment of the infants for six weeks. In the US this is still the standard of care. Very few physicians will accept any liability if the drugs are reduced. In fact 80% of the HIV women in Europe and the US are being treated with combination therapy- ie. two or more drugs. But in Thailand, for economic reasons, the amount of AZT was significantly reduced in a study group of women. Also the study tried to examine if there is a shorter and more effective way of treatment. The analysis done in this study revealed that the lower dose of AZT group received the same benefits as the regular dosage group i.e. the ACTG-076 group. This is remarkable, because it proves that the amount of AZT can be significantly reduced. A sub-group also emerged during the study - women who did

not receive the full course of treatment. Some groups were very critical of the placebo trials. However, the efficacy of the shorter course, where treatment was given for the first trimester, followed with treatment of the infant and no breast-feeding, has been established. The Thai CDC study had a reduction in transmission which was almost the same as 076. But one cannot really compare these two studies because a lot of things are different. The population is different in severity of AIDS but nevertheless the reduction in transmission of 50-60% was a much-heralded result. This was accomplished only with oral AZT therapy during labour and delivery and four weeks of treatment to the mother and none to the infant, but again with no breast-feeding. This was a very important study because it showed that we could reduce the amount of AZT which is very economical. However, it really does not address many of the issues which we face on a day to day basis. If a mother chooses to breast-feed we really do not have any answers on this shorter course of therapy, whether it will still be as effective. There are some questions that need to be answered and some of the subsequent speakers will be addressing this.

Now the announcement from South Africa that they are not going to provide even the shorter form of therapy to pregnant women is very disappointing. But it does point to a liability that we need to be careful of. We need to think very seriously here at this meeting about how to integrate the HIV care with other care. I do not think we are going to make the progress that we all expect to see as long as HIV remains segregated. We, out of necessity, have to see patients in separate areas. Many of the hospitals in Delhi and other cities in India are not admitting patients with HIV. Doctors are not operating on HIV-infected patients. That is an obstacle that must be overcome and it is related to the issues that we are discussing here, because without being able to implement a standard of care-good, prenatal care and integrating the HIV care into overall care - we are not going to see the type of reduction that we would want to see, even if we have anti-retroviral therapy available. Hence we must enlist the assistance of the rest of the medical community. It is extremely disappointing that one of the major obstacles in delivering care to the HIV patients is the medical community itself. This physicians become obstinate and stubborn. We talk much about the government obstacles, but the medical community is itself a major obstacle. And that is the obstacle that we must overcome if we have to see a reduction in HIV transmission and prevention in India as well as in other countries.

2. RESULTS OF OBSERVATIONAL STUDY AT CHENNAI - MODIFIED ACTG 076 REGIMEN

Dr. S. Parameshwari &. Dr. N.M. Samuel
Department of Experimental Medicine/AIDS Resource Centre
TN Dr. MGR Medical University

Over the past 12 years there have been many advances in the recognition, diagnosis and treatment of HIV infection in adults and infants.

Transmission of HIV infection from mother to infant can occur during pregnancy and labour, as well as through breast milk. Mother to child transmission of HIV represents a major cause of morbidity and mortality among young children, particularly in developing countries with a high prevalence of HIV infection. Prevalence of HIV in pregnant women ranges from 2-4% in Mumbai and 0.6% to 1% in Chennai. In 1994, the paediatric AIDS Clinical Trial Group 076 (ACTG-076) demonstrated the efficacy of a three-arm regimen of Zidovudine prophylaxis in reducing perinatal transmission of the Human Immuno-deficiency Virus (HIV) from 25-5% to 8.3% On the basis of this study, Zidovudine prophylaxis to reduce perinatal HIV transmission became the standard of care in many developed countries.

We in the TN Dr. MGR Medical University were excited that intervention to reduce HIV perinatal transmission was available and proceeded to implement the ACTG 076 protocol with modifications. An observational study was undertaken. In addition, the Anonymous Unlinked Screening of HIV Infection among Pregnant women was conducted at a government hospital at Chennai in 1996.

Objective

To evaluate the tolerability, safety, efficacy of Zidovudine in South Indian pregnant women and infants. In addition, to study the HIV-1 viral dynamics by estimating the plasma HIV-1 RNA levels.

Methodology

HIV positive pregnant women were referred to our department from different places like Tiruchy, Perundurai, Coimbatore, and Chennai, and were entered in the study. The clinical status was reconfirmed by the Western Blot test.

Zidovudine was given at 32 weeks of gestation and continued during labour and delivery, followed by 6 weeks of Zidovudine for the mother (postpartum) and for the infant.

Demographic information of the mother, mode of delivery, infant's data - age, sex, birth-weight - and follow up details were recorded in the proforma. All mothers and partners were counselled prior to recruiting them in the study.

The pregnant mothers were monitored till the time of delivery. Blood samples were taken before and after delivery from the mother. The infant was also screened along with the mother with the ELISA, Western Blot and CD4 CD8 tests. The viral load by RT PCR method(Roche) was performed for some of the mothers and infants. For infants, besides initial tests, blood was tested every four months by Western Blot and viral load.

Drug Administration

Zidovudine Dosage:

Mother:
Ante-partum-100 mg three times/day (6weeks)
Labour and delivery-200 mg 8 hourly.
Post-partum- 100 mg three times/day (6weeks)

Baby:
2 mg/per kg body weight/thrice/day (6weeks)

Results

Five pregnant mothers had normal vaginal delivery and three underwent caesarean section. The mothers and the infants were monitored for a period of 18 months following delivery. At the time of birth, all the 8 infants born to the HIV seropositive mothers weighed between 2.6 to 3.5kg. No congenital anomalies were detected.

At the 18 month follow up of 8 infants, one infant presented with erythematous papular rash and another presented with loose motions and fever. The other infants' development was normal as shown by normal milestone development and increase in the body weight.

The cost of the regimen, clinical features and laboratory test results are shown in Table 1, 2, 3 and 4.

Advantage of the regime

- Since 75% of paediatric HIV infection is from mother to child transmission, reducing the transmission of HIV infection from mother to child using this regime will in turn reduce paediatric HIV infection.
- This regime is easy to follow and can be replicated.
- This regime is cost effective. Money spent for the treatment of paediatric HIV infection is much more than the money spent for reducing the transmission of HIV infection.

Disadvantage of the regime

All mothers tolerated the drug except two mothers who complained of nausea. Haemoglobin and other routine investigations were within normal limits.

Other beneficial effects observed during the study:

Counselling

Besides pregnant mothers and their partners, other family members were also counselled. Counselling of the joint family members reduced the stigma and facilitated their acceptance as members of the family and community.

Training

Obstetricians and other members of the health team were trained to handle HIV positive pregnant women and infection control methods were adhered to at the time of delivery.

In this pilot study, it was not possible to restrict mothers from breast-feeding their infants. Culturally the mother is expected to breast-feed and due to family pressure, all mothers breast-fed their infants.

Conclusion

This modified ACTG 076 regimen is the first to be studied in India. This can be replicated in Indian settings. However the cost is still prohibitive for India but relatively cheaper than the original cost of ACTG 076 regimen as practiced in the USA. The spin offs have been the modified counselling practice adopted for the joint family which enabled the family to "accept" the infected mother and the infant. The second benefit was that obstetricians' practices during the conduct of deliveries have significantly improved, particularly in reducing the infections to the infant during labour and delivery. Studies are in progress to administer a combination of drugs to mothers and infants during labour and delivery as a large number of mothers seek hospital services only at the time of delivery.

Acknowledgements

We gratefully acknowledge the assistance of Dr. Mini Jacob and Mr. Viswanathan for performing the viral load assays.

Table 1: Cost of the Regimen

ZIDOVUDINE

Mother

Ante-partum (Before delivery)	
100 mg three times a day = (45 days)	135 capsules
Intra-partum (During delivery)	8 capsules
Post-partum	
100 mg three times/day	135 capsules

For the baby

2 mg/Kg body weight	
(45 days)	9 capsules

Total capsules needed

135+135+8+9 = 287

Each capsule = Rs. 50

287 capsules = Rs.287 x 50 = Rs. 14,350.00

For one pair (mother and infant) = Rs. 14,350.00
(= US $342)

TABLE II: SOCIO DEMOGRAPHIC AND OTHER PARTICULARS OF MOTHERS AND INFANTS IN THE STUDY

S.No.	Name	Age	Mode of Delivery	Breast Feed	Viral load of the infant at 18 months following birth
1.	A	28	Vaginal	Yes	No HIV - 1 RNA detected
2.	B	22	Vaginal	Yes	3,18,872 cp / ml
3.	C	26	Vaginal	Yes	Baby expired
4.	D	18	Vaginal	Yes	Baby expired
5.	E	24	Caesarian	Yes	No HIV - 1 RNA detected
6.	F	25	Caesarian	Yes	No HIV - 1 RNA detected
7.	G	28	Caesarian	Yes	-
8.	H	21	Vaginal	Yes	-
9.	I	24	N.D		
10.	J	23	"		
11.	K	25	"		
12.	L	20	"		

N.D. - Not Delivered

TABLE III : CLINICAL DETAILS OF THE INFANTS

S.No.	Baby's birth Weight	Progression in wt. gain	Congenital anomalies	Mile-stone	Diarrhoea	Skin lesions
1.	3.5kg	Normal	Nil	Normal	Nil	-
2.	3.0kg	Slow Progression	Nil	Delayed	Nil	Papular Rasheas
3.	2.6kg	Slow Progression	Nil	-	+	-
4.	2.5kg	Slow Progression	Nil	-	-	-
5.	3.5kg	Normal	Nil	Normal	Nil	-
6.	2.5kg	Normal	Nil	Normal	Nil	-
7.	3.0kg	Normal	Nil	Normal	Nil	-
8.	3.0kg	Normal	Nil	-	-	-
9.	ND	-	Nil	-	-	-
10.	ND	-	Nil	-	-	-
11.	ND	-				
12.	ND	-				

N.D. - Not Delivered

TABLE IV: LABORATORY DETAILS OF THE INFANTS AT BIRTH AND FOLLOW UP

S.No.	ELISA	WB*	CD4/CD8	Hb%	Viral load of the infant at 18 months following birth
1.	Reactive	+ve	1120/1218	11.5gm	No HIV - 1 RNA detected
2.	Reactive	+ve	1120/415	9.2gm	3,18,872 cp / ml
3.	Reactive	+ve	310/95	11.0gm	Baby expired
4.	Reactive	+ve	1185/2043	10.4gm	Baby expired
5.	Reactive	+ve	1023/1100	8.9gm	No HIV - 1 RNA detected
6.	Reactive	+ve	288/95	9.0gm	No HIV - 1 RNA detected
7.	Reactive	+ve	1040/1110	11.5gm	-
8.	Reactive	+ve	433/420	9.0gm	-

*WB - Western Blot

3. REVIEW OF ONGOING TRIALS FOR PREVENTION OF MOTHER TO CHILD TRANSMISSION OF HIV

Dr. Dorothy H. Bray
Glaxo Wellcome, HIV & 01 Clinical Development, UK

Current research

Strategies to reduce risk of perinatal HIV transmission include antiretroviral therapy, immunisation, modified obstetric practices, infant feeding practices and micronutrient supplementation.

ZDC therapy in ACTG 076 reduced transmission from 25.5% to 8.3% and established this regimen as a standard in many countries. Subsequently, other studies were initiated to investigate abbreviated modifications of ACTG 076. Harvard University is comparing in Thailand three different lengths of oral ZDC therapy (from wk 28 or 35, pre-, intra-, post-partum for mother and infant, no breast-feeding) to 076 regimen given orally, and has recruited 450/1500 patients. A recently terminated CDC study in Thailand in among the non-breast-feeding population has shown that simplified ZDV regimen (oral ZDC prepartum from wk 36 and intrapartum,with no treatment for the infant) is effective in reducing transmission from 18.6% to 9.2%. The relevance of these results to countries where breast-feeding cannot be easily substituted, is being tested by two large studies in the Ivory Coast: CDC study (n=1500; oral ZDC pre-partum from wk 36, intra-partum and post-partum with no treatment for infant) and ANRS 049 (n=780; oral ZDC pre-partum from wk 36, intra-partum and post-partum x1 wk, with no treatment for infant) Results of both studies are likely to be available during early 1999. HIVNET 012 study in Uganda (n=750, breast-feeding allowed) is comparing ZDV short regimen (intra-partum for mother, infants; ZDV X 7d) with NVP (one dose for mother during intra-partum, one dose for infants at 72h post delivery).

While ZDV's efficacy has been estabilslhed, it is hoped that a combination therapy will be even more effective. Hence there are a number of studies investigating adding other antiretrovirals to ZDC. ANRS 075 in France has recruited 450 patients into 1 arm open labelled study in which 3TC was added to ZDV and 3TC for 6 wk 32) during pre-partum but not during post-partum (infants received ZDV and 3TC for 6 wks). Analysis of results is in progress and planned to be completed at the end 1998. The WHO/UNAIDS sponsored study PETRA has also com-

pleted recruitment (n-1900). The study looks at three ZDV/3TC regimens, starting at wk 36:1 /pre-, intra-, and post-partum (1 wk for mother and infant); 2/intra- and post-partum; 3/intra-partum only, comparing these to placebo arm (terminated in Feb 98). Results from the interim analysis of this study are likely to be available during early 1999. Pharmacokinetic studies are being conducted with ZDV/3TC/Nelfinavir results expected in 1999.

Immunisation techniques are in the very early stages of development (phase I study in newborns with Alvac Vaccine) and more work is required to assess the usefulness of this approach. The European Collaborative Group has been looking at caesarean vs vaginal modes of delivery. Elective cesarean has been shown to result in reduction of transmission but it is not certain whether this intervention is beneficial regardless of the maternal viral load and whether it will provide additional benefits in women treated with combination therapy. The role of vitamin A supplementation also remains unclear with conflicting results reported and research continuing in Malawi, Zimbabwe and South Africa.

4. IMMUNOLOGICAL ASPECTS OF PERINATAL HIV TRANSMISSION

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Maternal-infant transmission of HIV can occur during pregnancy, at the time of delivery and after birth through breast-feeding. The majority of infections appear to occur during labour and delivery, thereby providing a unique window of opportunity for intervention to prevent the transmission as has been shown by several studies. A number of intervention trials are ongoing in various parts of the world including the United States to test this hypothesis. The major virus forms that are transmitted utilise the chemokine co-receptor CCR5 thereby suggesting that the cellular targets of infection preferentially express this chemokine co-receptor. The maternal viral load is an important determinant of HIV transmission, but little information exists about maternal immunological correlates of HIV transmission. Low maternal CD4 counts are associated with increased transmission risk, but the correlations are not as that with virus load. From the side of the infant, host genetic factors and immune responses undoubtedly play a role in transmission. There is data to suggest that HIV exposed uninfected infants exhibit HIV specific cellular immune responses. Genetic factors which influence chemokine co-receptor expression pattern can play a significant role in HIV transmission. More information exists about factors related to disease progression in infected children. Besides the adverse correlation with high virus burden at birth and during early infancy, genetic factors that determine HLA and chemokine co-receptor expression can play a role in delaying or accentuating disease progression. Immunological characteristics associated with disease progression in HIV infected children include loss of CD4 cells, loss of native T cells, indicating thymic deficiency, expression of activation markers eg. DR and CD38 on CD8 T cells, increased lymphocyte apoptosis, decreased HIV specific and non-specific cellular immune responses, alterations in T cell receptor repertoire, hypergammaglobulinemia and deficient specific antibody formation. How the course of HIV disease will change with the advent of highly active anti retroviral therapy is currently under investigation. Initial experience suggests that effective virological suppression ultimately leads to recovery of the immune system but it is unknown if immunological recovery is complete and how long it takes. Strategies to facilitate immunological reconstitution are currently under study.

5. RESULTS OF MODIFIED ACTG-076 PROTOCOL - THE IHO-WADIA MODEL

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Background

Since January 1999, we have tested more than 65000 pregnant housewives belonging to the middle socio-economic strata of society and have noted an average sero prevalence of 1.34% in this low risk population. For the first two and half years of our programme, no interventional strategy was initiated and the rate of mother to child transmission noted was approx. 22%. Since mid-1995 we devised our own protocol (the IHO-WADIA Model) for prevention of vertical transmission.

Objectives

The present study evaluates the efficacy of an innovative regime to analysis the success of using a shorter course with lower doses of AZT to pregnant women, oral powder AZT to infants, elective caesarean section delivery and avoidance of breast-feeding in reducing vertical transmission of HIV.

Methods

A prospective study of HIV infection in pregnant women and their infants has been going on at the Wadia Maternity Hospital since January 1993. Since mid-1995 a proportion of these women were offered perinatal interventional in the four arm protocol constituting of (i) administration of 400mg AZT per day for at least last 6 weeks of antenatal period, (ii) delivery by elective Caesarean section, (iii) oral AZT powder 0 mg/kg/day to the infant tor 6 weeks and (iv) avoidance of breast milk.

Result

102 mother-infant pairs fulfilled all entry criteria of which in only 58 infants could a definitive diagnosis of their infectivity status be ascertained. Only 4 of 58 infants tested HIV positive between 15 to 18 months giving this regime success rate of 93%.

Conclusion

This intervention significantly reduced mother to child transmission. These results need to be substantiated by larger studies using a similar design. The present study reports that in a largely urban population of a developing country, implementation of these perinatal interventional strategies resulted in reduction of vertical transmission from 22% to 7%, a rate comparable to that achieved by the original ACTG-076 protocol. On the basis of these results HIV seropositive pregnant women should be counselled and offered the benefit of the IHO-WADIA model in settings similar to these.

6. RESULTS OF CLINICAL TRIALS IN THAILAND

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Mother-to-infant transmission is the most common cause of HIV-1 infection in children; and its rate ranges from 13 to 50%. ACTG 076 achieved a reduction in mother-to-child transmission ofHIV-1 from 25% in the placebo-group to 8% in the AZT receiving mother/infant pairs. Since the affordability of that regimen was questionable, particularly for developing countries, a recent published study conducted in Thailand suggested that short-term AZT (beginning as late as 36 weeks gestation) for the mother alone, with oral instead of IV therapy during labour, was as successful in reducing the transmission rate from 19 to 9%. The treatment costs were US$50. -versus US$800 (ACTG076). These results are encouraging because prophylactic therapy may become more affordable and available throughout the developing world. Since current anti-retroviral regimens are not 100% elective in reducing perinatal transmission rates, alternative approaches are being tested. Data from European studies suggested that caesarian section might be an advantage over vaginal delivery. Duration of membrane rupture is identified as another important factor in various clinical studies. A number of clinical trials using different anti-retrovirals as single agent or in combination therapy have been conducted in Thailand. Data from these studies will be presented with an update on the ongoing interventional projects.

7. CURRENT TECHNIQUES USED IN THE DIAGNOSIS OF HIV INFECTION IN INFANTS AND RELEVANCE OF VIRAL LOAD IN PERINATAL TRANSMISSION

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Problem

Women infected with HIV transmit the virus to their infants either perinatally or through breast milk. Overall, the rate of transmission without intervention is about 30%. Maternal anti-HIV is present in the infant's serum making it impossible to identify infection in the infant using HIV-antibody tests, in fact, anti-HIV tests can only be used after 18 months for a definitive and anti-HIV diagnosis.

Methods and results

	Technical effort	Cost	Reliability at two weeks	Reliability at three months
Culture	High	High	Variable	Variable -High
DNA	High	High	Highest	High
RNA	High	High	High	High
p24 Antigen	Medium	Moderate	Moderate	High
IgA	Low	Moderate	Variable-low	Variable
IgG	Lowest	Low	Low	Low

Clinical and testing algorithms need to be developed further to avoid false results.

Validation and quality assurance are not conducted to a sufficient standard. All assays should be conducted on two separate specimens before a diagnosis is made. Diagnosis may be confounded by therapy in the perinatal period.

Conclusion

A number of methods are available to diagnose HIV infection in infants of various ages. However for quality results, false reactivity must be controlled. Lower costs and reliable methods for use in under-resourced countries should be developed urgently.

8. TOWARDS THE FORMULATION OF A NATIONAL POLICY ON PREVENTION OF PERINATAL TRANSMISSION OF HIV

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WHY DO WE NEED A POLICY?

A policy is needed to show us the direction in which we should proceed. Public health policies are primarily guided by the assessment of public health importance of the problem. In this context we generally ask four questions.

- How common is the problem?
- How serious is it?
- Can something be done about it?
- How much is it going to cost?

It is often difficult to get a good mental picture about the relative frequency of a disease in the Indian situation. Whatever the prevalence of the condition, when you multiply it by the total population, the answer usually is in terms of hundreds of thousands or millions. If you live in Bhutan where the total population is 500,000, most diseases will seem to have a frequency which merits little attention.

I would like to change the way we look at the overall frequency and seriousness of the problem by using another term, namely, "population attributable risk". The question we would like to ask is : "of all the child deaths in India what proportion is due to HIV/AIDS?" This is an important parameter in assessing the public health importance of a problem which allows us to estimate the potential impact of any planned intervention.

The population attributable risk is a function of two parameters:

- The prevalence of HIV among pregnant mothers.
- The relative risk for child death due to HIV (what extent HIV infection increases the risk of death among children)

We know that the risk of death among children acquiring HIV perinatally is close to 1 by the age 10. This we need compare with the risk of death of a child born to

an HIV positive mother without acquiring perinatal infection. Many of them may have sick fathers or no father at all. Their mothers may also fall ill very soon. If one were to add to this the added risk of death if breast-feeding were to be denied to them, I suspect that the relative risk for HIV deaths alone is not likely to be more than two.

$$\text{Population attributable risk} = \frac{Pe(RR-1)}{Pe(RR-1)+1}$$

Thus, if 1% of the women are infected
then the population attributable risk will be $\frac{0.01\ (2-1)}{[0.01\ (2-1)]\ +\ 1} = <1\%$

In other words, less than 1% of child deaths can potentially be prevented if the rate of perinatal transmission can be brought down to zero. This however cannot be achieved at present. What then can be done in this context? Identification of pregnant women with HIV followed by administration of AZT can bring down the perinatal transmission rate by 66% to 55% depending on the schedule used. This assures 100% coverage and 100% compliance.

Even under ideal conditions, the overall reduction in mortality is likely to be less than what has been estimated above as population attributable risk.

We look after a population on 100,000 where anonymous testing of antenatal women have been carried out and the prevalence was found to be less than 2/1000. In many parts of rural Tamil Nadu, I expect the prevalence of HIV infection among pregnant women to be around this figure. I also work with a group of commercial sex workers among whom the prevalence of HIV infection is around 66.6%. In the same area, 12 out of 15 unmarried young men were found to be HIV positive.

What we see around us is micro epidemics of HIV infection with the disease showing a high degree of clustering. The overall impact of any planned programme will essentially depend on the prevalence of infection. But we need to bear in mind that even in sub-Saharan Africa with a prevalence of 10%, the overall impact on perinatal transmission through AZT administration was only 12%.

Would I then be interested in implementing a programme for controlling perinatal HIV transmission in my population of 100,000? Let us take an area where the

prevalence of HIV is 5/1000 and use a diagnostic test with 99% sensitivity and 99% specificity. Along with the 5 true positive cases, I will pick up 10 others as false positives. So in a low prevalence situation we will be obliged to do multistage screening. In a country where about 37% live at or below the poverty line, the cost involved in universal testing and treating to prevent HIV transmission seems unaffordable.

Alfred Sommer and his colleagues carried out a study of Nepal on the usefulness of high dose Vitamin A supplementation in preventing childhood mortality. They concluded that the control group had 30 to 40% higher mortality as compared to the supplemented group regardless of their age or nutritional status (Table 1).

EFFICIENCY OF VITAMIN A IN REDUCING PRE-SCHOOL CHILD MORTALITY

6-11 months			
	Vit.A	Contorl	RR
Malnourished Well nourished	4.6 % 1.3 % (3.5)	6.6 % 1.8 % (3.7)	1.4 1.4
12-72 months Malnourished Well nourished	6 % 0.4 % (1.5)	8% 0.7% (11.4)	1.3 1.75

However, if one were to compare the malnourished group with the well nourished group, one would see that malnutrition increases the risk of death 4 to 11 times. Given this evidence, would you rather settle for a Vitamin A supplementation programme or a comprehensive integrated nutrition programme? Scientific evidence is often looked at in a manner that only highlights simple interventions. Life is much more complicated than that. Please do not think that I am fighting against any intervention against perinatal transmission. I am just trying to open up our minds so that we can think in a comprehensive manner and come to a logical conclusion relevant for our people.

Pope John Paul, after his visit to India, was asked to comment on certain issues pertaining to this country. He is reported to have said, "Whatever you say about India can be absolutely right and absolutely wrong at the same time." This is indeed a large country with considerable heterogeneity.

Problems and their solutions cannot be the same in Tamil Nadu, Kerala and Manipur.

How, then, do we go about formulating a national policy? The best policy, it appears to me, is not to have a national policy but to encourage development of a more decentralized policy-making process. Each area should be able to evolve its own policies based on its priorities.

The concept of Health System Research may be useful in this context. HSR is a continuous process of research aimed at improving the quality of the health system in an area. We need to impart skills in HSR to health professionals so the formulation of policies and action plans are based on sound scientific evidence and the evaluation focuses on the cost effectiveness of intervention.

At present the endeavours for reducing HIV transmission rates in the general population is far from satisfactory. In Tamil Nadu, there are hospitals where up to 20 individuals receive injections with the same needle and syringe. The safety measures in labour rooms and operating theatres are far from satisfactory.

I feel that we should be cautious in looking at the issue of perinatal transmission as an isolated issue. I hope that the issue will be seen in the context of the overall scenario of HIV epidemic in a country which is quite unequally developed.

9. PLACEBO CONTROLLED TRIALS FOR PREVENTION OF PERINATAL TRANSMISSION OF HIV : SCIENTIFICALLY JUSTIFIED?

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Background

In February 1994, the NIAID interrupted the ACTG study 076 because preliminary analysis revealed a significant and dramatic difference in vertical transmission in women receiving ZDC vs those receiving placebo (25.5% vs 8.3%). This treatment became the standard of care in the US and other developed countries. However, the cost per patient for prophylactic treatment (US $ 800 for ZDV alone) was not affordable in developing countries where the problem of perinatal HIV was highest.

In June 1994, a special consultation of the WHO called for the launching of studies to determine whether radically cheaper alternatives to the ACTG 076 regimen could achieve some measure of reduction of perinatal transmission. Sixteen placebo-controlled trials were launched, 9 funded by NIH/CDC, 5 by other governments and 1 by UNAIDS.

A controversy erupted in 1997 about the ethics of conducting trials using placebo when it was clearly proven that use of ZDV during pregnancy, during labour and in the neonatal period would reduce perinatal transmission. It was the contention of some that the ethical standards applied to research in developing countries should be no less exacting than they would be in the case of research carried out in the sponsoring country. They argued that on the basis of ACTG data and pharmacokinetic data, there was every reason to believe that a well-designed short course of ZDV regime would be more effective than placebo. These findings seriously disturb the equipoise (uncertainty over the likely study result) necessary to justify a placebo-controlled trial. Therefore, the use of a placebo arm in any trial to reduce perinatal transmission would be unethical. They pointed out that "nothing" is a description of what happens; "standard of care" is a normative standard of effective treatment, whether or not it is provided in a community. It was their opinion that residents of impoverished, post-colonial countries must be protected from potential exploitation in research. Otherwise, the abominable state of health

care in these countries can be used to justify studies that could never pass ethical muster in the sponsoring country.

Those who supported the use of the placebo arm in these trials were of the opinion that research done in developing countries should address the needs of the people living in those countries. While it was agreed that trials that make use of impoverished populations to test drugs for use solely in developed countries violate our most basic understanding of ethical behavior, it was felt that trials that apply available knowledge to interventions that can benefit such populations are appropriate.

Available data suggests that shorter courses of ZDV would not be as effective as the ACTG regimen. Therefore, an equivalency trial using the ACTG 076 regimen would most likely show that the shorter regimen is less effective than ACTG 076 regimen but would not provide data on its effectiveness as compared to placebo. If the ethical principles suggested by those that argue against placebos are applied in developing countries, no further trials may be possible unless one can come up with a low cost intervention which has a similar or higher efficacy that the ACTG 076 regimen. Failure to conduct trials which will have some benefit, albeit lower than that of the ACTG regimen, will result in nothing being done at all to prevent perinatal transmission in poor countries which have a major problem related to perinatal HIV transmission, which in itself would be unethical.

What is the solution? How then can we make a decision on performing trials in our country? One must appreciate the debate initiated by those who opposed placebo-controlled trials. However, the final decision must be taken by those in the countries concerned and not dictated by those with an inadequate understanding of the situation faced by those in developing countries.

There is no denying that HIV is a rapidly increasing problem in our country. Using an HIV prevalence of 0.5%, one can expect 125,000 infants born to HIV infected mothers per year, with a resultant 31,250 infected infants born each year (this number is likely to increase). Having decided that there is a major problem, one needs to consider whether there is a need for further trials or if there is sufficient data to plan our public health strategies.

Trials that have thus far shown benefit involve screening of antenatal women for HIV. Based on the results of available trials, evaluating anti-retrovirals in preg-

nancy, we would need to treat 11 HIV-infected mothers to prevent 1 case of peri- natal transmission. With an HIV prevalence of 0.5%, we will need to screen and counsel 2200 pregnant women at a cost of Rs. 3.52 lakhs to prevent 1 case. Moreover, in the Thai trial, participants were asked not to breast-feed. Denial of breast-feeding in most populations in India would result in an increased mortality, which may outweigh the benefits of prevention of transmission. Therefore, the currently suggested interventions will not be a cost-effective public health program in India, and would divert scant resources needed for other programmes. There is a need for trials of interventions that can be applied universally in India and trials evaluating alternative, less expensive interventions are necessary. Since these are likely to be less effective than the ACTG 076 regimen, the use of a placebo arm may be necessary to prove that they are better than nothing.

But in planning any trial in an impoverished country, one needs to carefully consider whether the population on whom the study is being conducted will benefit from the results of a trial. If the regimen being tested cannot be delivered to the population on whom the test is being conducted, the beneficiaries will be those in developed countries or sections of populations in our own country who are economically advantaged, and not the population in the trial. This will be clearly unethical. Thus, there must be a commitment and a real plan on how the intervention will be delivered to the population should it prove successful. Without this, there can be no justification for the trial.

10. BREAST-FEEDING PROMOTION IN INDIA IN THE CONTEXT OF THE HIV EPIDEMIC

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It is a terrible dilemma that something as important for child health as breast-feeding should also be able to transmit a fatal infection. Despite the difficulty of studying the timing of transmission of HIV from mother to child, we have sufficient evidence to be sure that breast-feeding contributes a substantial additional risk when the mother was infected before or during the pregnancy, and a significant risk when the mother becomes infected during the period of lactation[1], However we do not have reliable estimates for these risks. The majority of breast-fed babies born to HIV positive women do not become infected with HIV.

In May 1998, WHO, UNICEF and UNAIDS published new guidelines which recommend that pregnant women be counselled and tested for HIV, and that those infected be counselled about the risk of breast-feeding and if possible, helped to provide an adequate alternative, even in developing countries[2,3]. This contrasts with their earlier recommendation that 'Breast-feeding should be recommended to HIV infected women in areas where infectious diseases and malnutrition are the main causes of infant deaths and infant mortality is high'[4].

The other intervention being discussed widely is the administration of a short course of Zidovudine during pregnancy, with avoidance of breast-feeding, to reduce the risk of mother to child transmission[5].

These two interventions offer some hope but raise many questions for countries that cannot afford to counsel and screen all pregnant women, and provide Zidovudine and infant formula to those who are positive. They require changes in behaviour during pregnancy and infant feeding-times of great cultural significance. They require resources and health care structures which are not widely available at present. There is potential for these interventions to cause harm as well as benefit, and there is an obligation on us when discussing policy to consider possible adverse effects and now they might be avoided or at least minimised.

Both these interventions require a policy of offering voluntary counselling and testing for HiV to all pregnant women. The offer of a test may cause anxiety and family conflict over making the decision; the results may lead to stigmatisation,

isolation secret-keeping and the possibility of violence or expulsion from the family.

Babies who are not breast-fed will have a much higher risk of diarrhoea, respiratory infections, malnutrition and death[6,7]. The protection provided by breast-feeding becomes more important the poorer the setting. And the HIV epidemic itself increases poverty. A woman who does not breast-feed may meet with social disapproval. She may also be stigmatised if she is assumed to have HIV because she does not breast-feed. Women themselves often have strong feelings about breast-feeding and may find it distressing not to breast-feed, especially if the decision has been made by health professionals or by the husband or his mother. Women who do not breast-feed will have a rapid return of menses and fertility, and need access to advice and contraception. Avoidance of breast-feeding will also place an economic burden on families. Ideally a lactating woman needs an extra 500 calories a day. Five days worth of extra food costs less than 20 rupees, by comparison a five day supply of formula costs about 170 rupees[8].

To avoid these harms, we need to gather more information about attitudes towards counselling and testing and how to provide appropriate counselling so that women can make informed choices. When young married women have little autonomy what does 'informed choice' mean? Should the family be involved in the decisions? What is the meaning of confidentiality in this context? The answers have to take into account public opinion. We also need information about practical, safe, affordable, and appropriate alternatives to breast-feeding, and the impact on women and babies of not breast-feeding. There is much diversity within India and the answers to these questions will vary. I believe that the best way to answer these questions is to use participatory research methods that have been developed so well in India[9]. Put simply, we need to go and ask women. We can use various tech- niques to stimulate discussion - but I think that it is vital that we return to the women with our interpretation of what they have said to check that our interpre- tation is accurate.

There is also the danger that in pursuing these interventions other important measures that will reduce the number of infected babies but do not depend on knowing a woman's HIV status, will receive less attention and resources. These measures will benefit the health of women and children whether or not they are infected with HIV. We can think of such actions at different stages: before a couple meet, when a woman or a couple plan to conceive a baby, during pregnancy, at

delivery and after delivery. The measures include improving access to information, contraception, male and female condoms, and good ante-natal care, improving nutrition during pregnancy, and particularly avoiding deficiencies of micronutrients; early treatment of STDs and other infections; wiping the birth canal with chlorhexidine at delivery and minimising interventions such as artificial rupture of membranes and episiotomy. We need to advise against giving the newborn baby anything by mouth other than breast-milk because it inflames the gut and so increases the risk of transmission of HIV. After the baby is born there is commonly a period of sexual abstinence when men may be more likely to have sex outside marriage. They may put themselves at risk of becoming infected with HIV, and subsequently infect their wife. A few weeks after infection, viral levels in the blood are high and the baby will be at risk of becoming infected through breast-feeding. The time of delivery offers an important opportunity to give the father advice about the importance of using condoms or remaining abstinent to protect the health of his wife and baby. Many men feel a new sense of responsibility with the birth of a new baby. There may be ceremonies or events around the time of birth which could be used as an opportunity to counsel and provide information and condoms. It is important to document experiences of communicating with men about these issues.

We need to raise community awareness of the benefit of planning pregnancy because there are actions that a couple can take before and during pregnancy to reduce the risk of HIV infection in the baby. We also need to raise awareness of the need to avoid pregnancy when a woman is chronically ill, whether the cause of illness is known to be HIV or not.

When there is no safe alternative to breast-feeding we can recommend a shorter duration of breast-feeding, since some babies become infected with HIV after many months of breast-feeding, when their health is less dependent on the protection of breast-feedings[10]. We should also advise mothers with HIV to stop breast-feeding, at least temporarily, and express their milk if they have a breast problem such as cracked nipples, mastitis or an abscess. It is important that an HIV positive mother does not become re-infected with HIV while she is breast-feeding because this may increase the risk to the baby. She should be encouraged to use female condoms or supported to persuade her partner to use condoms.

The need for alternatives to breast-feeding will increase both because of women trying to prevent passing the virus to their baby and because there will be babies

who have mothers too ill to feed them or who have died of AIDS. Where HIV prevalence is high the government will not be able to afford to supply commercial infant formula for all babies who need it. It is therefore important to explore other possibilities. It is possible to make home-made formulas from animal milk. Unmodified cow's milk can damage the baby's kidneys and irritate the gut. Cow's milk has too great a proportion of protein. To make 150 ml of formula for a baby from birth to six months 100 ml of cow's milk should be added to 50 ml of water and 10 grams (2 teaspoons) of sugar[12]. This should then be boiled. Such formulas lack micronutrients. Sachets containing appropriate concentrations of micronutrients are likely to become available to add to these formulas. In settings where many women are infected with HIV we need to explore the potential for women to co-operate in the safe production of home made formula. It may be cost effective for one woman in a group to be trained to produce formula under hygienic conditions and sell it to other mothers at low cost.

Another possibility is for women to express their own milk and boil it before giving it to the baby. Heat will kill the virus. Some people fear that pasteurisation or boiling destroys the value of breast-milk. However, although some of the anti-infective properties are reduced, many important components are unaffected and heated breast milk is nutritionally superior to other milks. We do not know whether women will be able to sustain expressing their milk for six months or more when they have never been able to put the baby to the breast. Again, there may be potential for women to co-operate in expressing and pooling their milk before pasteurisation or boiling. To pasteurise the milk it should be heated to 62.5oC for 30 minutes, or it can be boiled and then cooled immeditely[2]. We need to ask women about practical ways to heat breast-milk. Perhaps we need to design a small, long handled pan with a lid to make it easy to heat small quantities of breast-milk at the same time as the family dinner.

Whichever replacement milk is used, it is important that the mother or carer is taught how to use to a cup to feed the baby. Babies of any age can be fed milk using a cup. A cup is simple to clean thoroughly and does not need to be sterilised. Bottles and teats are very difficult to clean and increase the risk of diarrhoea.

There is a danger that interventions to prevent transmission of HIV will have a damaging effect on breast-feeding rates in the whole community. When women and their families become aware that breast-feeding is able to transmit HIV they may decide not to breast-feed in case they have HIV or may become infected. If

educated women such as teachers and nurses start to artificially feed their babies others begin to think that infant formula is superior to breast-feeding. WHO and UNICEF have therefore emphasised the need to protect, support and promote breast-feeding at the same time as implementing strategies to reduce the risk of babies becoming infected with HIV[2].

In India, although a decline in breast-feeding is occurring with urbanisation and industrialisation, the vast majority of babies, about 85%, are still breast-fed. However, rates of exclusive breast-feeding for the first 6 months are low, pre-lacteal feeds and delayed initiation of breast-feeding are common, and late introduction of solids is also common[11,12]. Supplements tend to be given with a bottle and teat.

India has an excellent record of protecting, promoting and supporting optimal breast-feedings[13]. There are a range of breast-feeding advocacy groups including the South Asia Breast-feeding Promotion Network of India, the Voluntary Health Association of India, the Association for Consumers Action of Safety and Health, the Coalition for Protection of Women and Children, and the Indian Academy of Paediatrics.

India is one of the few countries that have enacted legislation that implements the International Code of Marketing of Breast-Milk Substitutes in its entirety, as called upon by the World Health Assembly. The infant Milk Substitutes, Feeding Bottles and Infant Foods Act passed into law in 1992 and has sanctions of fines and imprisonment. The Act has empowered NGOs and government to take action to prevent marketing practices that compromise the health of children[14]. India also has 1017 Baby Friendly Hospitals. A hospital is accredited as 'Baby-Friendly' when staff do not distribute or otherwise promote artificial baby milk and agree to implement specific steps to support breast-feeding. These initiatives are now more important, as is the training of health professionals in both the advantages and physiology of breast-feeding[15] and the facts about transmission of HIV.

If our attempts to reduce the number of babies suffering from HIV infection are not to cause more harm than good we need to take a cautious and staged approach to the implementation of short-course Zidovudine prophylaxis and avoidance of breast-feeding, and use the enthusiasm and excitement stimulated by these new interventions to improve health care services for women more generally.

References

1. Dunn DT; Newell ML; Ades AE; Peckham CS. Risk of human immunodeficiency Virus type 1 transmission through breast-feeding. Lancet, 1992, 340(8819): 585-8.

2. WHO, UNICEF, UNAIDS. HIV and Infant Feeding: a guide for health care managers and supervisors. May 1998. Available from Programme of Nutrition, WHO, Geneva, Switzerland, or the UNAIDS website. (WHO/FRH/NT/CD/98.2).

3. WHO, UNICEF, UNAIDS. HIV and Infant Feeding; guidelines for decision-makers May 1998. Available from Programme of Nutrition, WHO, Geneva, Switzerland, or the UNAIDS website. (WHO FRH/NT/CD98.1).

4. Consensus statement from the WHO/UNICEF consultation on HIV transmission and breast-feeding. Weekly Epidemical Record 1992;67(24):177.

5. Nathan Shaffer, C. Bhadrakom, W.Siriwasin. R. Chuachoowong, P.Mock, N.L. Young, S. Chearskul, T. Chotpitayasunondh, J. Karor, R.J. Simonds, T.D. Mastro. Administration of Zidovudine During Late Pregnancy and Delivery to Prevent Perinatal HIV Transmission - Thailand, 1996-1998. MMWR, 1998:47(08).

6. Victoria C, Smith PG, Vaughan JP et al. (1987) Evidence for protection by breast-feeding against infant deaths from infectious diseases in Brazil. Lancet 1987; ii:319-321.

7. Editorial. A warm chain for breast-feeding Lancet 1994; 344: 1239-1241.

8. Nutrition commentary, UNICEF 1997.

9. Networking patterns: using PLA for obtaining sensitive information. Dr. Ravi Jayakaran, World Vision of India. 47, Fatima Nagar, Pune 411 013.

10. Nagelkerke NJ; Moses S; Embree JE; Jenniskens F; Plummer FA. The duration of breast-feeding by HIV-1-infected mothers in developing countries: balancing benefits and risks. J Acquire Immune Defic Syndr Hum Retroviral 1995:58:176-81.

11. Banapurmath CR; Nagaraj MC; Banapurmath S; Kesaree N. Breast-feeding practices in villages of central Karnataka. Indian Pediatr, 1996; 33(6)477-9.

12. Deshpande SG; Zodpey SP; Vasudeo ND. Infant feeding practices in a tribal community of Melghat region in Maharashtra state. Indian J Med. Sci, 1996; 50(1):4-8, 21.

13. Present day concepts on promotion of breast-feeding in India. Anand RK. Indian Paediatrics 1993; 30:1277-1283.

14. Kumta NB. Why the act? Indian Pediatr, 1995; 32(7):783-5.

15. Fidler K; Costello A. The role of doctors in influencing infant feeding practices in South India. Trop Doct, 1995;25(4):178-80.

II. MICRONUTRIENT INTERVENTIONS AMONG HIV INFECTED WOMEN AND CHILDREN

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Poor maternal micronutrient status has been associated with faster clinical and immunological progression of HIV-1 disease in non-randomised prospective studies, and could result in adverse birth outcomes, and increased risks of vertical transmission of HIV infection. Adequate vitamin intake leads to enhancement of epithelial integrity and systemic immunity, and could contribute to improved clinical condition among HIV infected subjects and reduce vertical transmission by reducing the risk and severity of opportunistic infections, and reducing viral load in blood. Adequate vitamin status may also reduce vertical transmission through the intra-partum and breast-feeding routes by reducing the HIV viral load in lower genital secretions and breast milk respectively.

Evidence to support these findings has been obtained from a few randomised placebo controlled trials. In a large trial among HIV positive pregnant women from Tanzania, we found that multivitamin supplementation resulted in large and significant reductions in the risks of foetal death, low birth weight and severe prematurity, and significant improvements in CD4 and CD8 cell counts. In another placebo-controlled trial among children from Tanzania, Vitamin A supplements resulted in a large reduction in mortality among both HIV infected and uninfected cilildren. There are a number of ongoing trials to examine the efficacy of nutrinonal supplements on the vertical transmission and clinical progression of HIV disease.

12. RESULTS OF PMPA IN REDUCING PERINATAL TRANSMISSION: LESSONS FROM THE SIMIAN IMMUNODEFICIENCY VIRUS - NEWBORN MACAQUE MODEL

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Background

Simple and affordable intervention strategies are needed to reduce the rate of HIV transmission from mother to infant in developing countries. Because of its many similarities, simian immunodeficiency virus (SIV) infection of newborn rhesus macaques is considered to be a useful animal model of human paediatric HIV infection to explore novel intervention strategies to prevent perinatal transmission. We have previously demonstrated that a 6-week AZT dosage regimen was partially effective in protecting newborn and infant macaques against SIV infection (1,2); we then used this animal model to test if more potent drugs, such as PMPA, can be effective even when a short regimen is used.

Objective

To investigate whether short-term 9-[2-(phosphonomethoxy)-propyl] adenine (PMPA) administration can protect newborn rhesus macaques against perinatal SIV infection.

Design and methods

Newborn macaques were inoculated orally with a 100% animal infectious dose of highly virulent SIV within the first 3 days of life. Twenty animals were untreated controls. Other animals were given various pre- and post-inoculation PMPA dosage regimens.

Results

All twenty untreated control macaques became persistently SIV-infected. PMPA was highly effective in preventing SIV infection. In a first study, 4 animals were given 2 weeks of PMPA treatment (30 mg/kg once per day, subcutaneously) start-

ing immediately after virus inoculation: only 1 of these 4 animals became persistently infected, while the other three animals, although they had signs of an abortive/transient infection, were virus-negative and seronegative at 8 months of age (3). In an effort to try to identify a shorter PMPA treatment regimen, 4 animals were given a first dose of PMPA (30 mg/kg) 4 hours before virus inoculation, and a 2nd dose of PMPA 24 hours later; all 4 animals were protected against infection, and are SIV-negative at 18 months of age (4). Preliminary results suggest that 4 mg instead of 30 mg PMPA/kg body weight is still effective; four newborn rhesus macaques were given 2 doses of PMPA (at 4mg/kg body weight), at 4 hours before and 20 hours after oral SIV inoculation; three of these four animals are SIV-negative at 7 months of age. When four newborn macaques were given 2 doses of PMPA (at 4mg/kg body weight), at 1 hour and 25 hours after virus inoculation, 2 of the 4 animals were virus-negative and seronegative at 7 months of age.

Conclusion

These studies suggest that 2 low doses of PMPA can be effective in preventing infection of newborn macaques; preferably, the first dose of PMPA should be given prior to virus exposure. It has been demonstrated that PMPA efficiently crosses the primate placenta, in addition, phase I/II of human trials in HIV-infected adults have demonstrated that short-term PMPA administration has strong antiviral activity in HIV-infected adults and was safe. Altogether, our data strongly suggests that short-term administration of PMPA to HIV-infected pregnant women at the onset of labour and to their newborns after delivery may reduce the rate of intrapartum HIV transmission. Several human clinical trials are currently being planned to determine the potential use of this regimen in reducing perinatal HIV transmission.

References

1. Van Rompay KKA, Marthas ML, Ramos RA, et al. Simian immunodeficiency virus (SIV) infection of infant rhesus macaques as a model to test antiretroviral drug prophylaxis and therapy: oral 3'-azido-3' deoxythymidine prevents SIV infection.

   Antimicrob Agents Chemother 1992; 36:2381-2386.

2. Van Rompay KKA, Otsyula MG, Marthas ML, Miller CJ, McChesney MB, Pedersen NC. Immediate zidovudine treatment protects simian immunodeficiency virus-infected newborn macaques against rapid onset of AIDS. Antimicrob Agents Chemother 1995; 39:125-131.

3. Van Rompay KKA, Marthas ML, Litson JD, et al. Administration of 9-[2-(phosphonomethoxy) propy l] adenine (PMPA) for prevention of perinatal simian immunodeficiency virus infection in rhesus macaques. AIDS Res Hum retroviruses 1998;14:761-773

4. Van Rompay KKA, Berardi CJ, Aguirre NL, et al. Two doses of PMPA protect newborn macaques against oral simian immunodeficiency virus infection. AIDS 1998;12:F79-F83.

13. TESTING AND COUNSELLING OF REGISTERED AND UNREGISTERED MOTHERS

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I would like to thank the MGR Medical University and Department of Experimental Medicine and Dr. Samuel for giving me this opportunity to share my experiences with you. So far, we have listened to a lot of research work done. My topic is down to earth, about what is the ground reality here in Chennai.

At the centre where we work, we do not use the word 'AIDS' anywhere. The word has a stigma attached and people hesitate to utilise services.

Everyday 4 to 5 people drop in for counselling and per month, I meet 4-5 pregnant women who are HIV positive.

We talk about counselling. What does counselling mean to people in India? We say that confidentiality should be maintained in HIV testing and the results should be told only to the person concerned.

Let me illustrate one such case:

A 19 year old woman, married for 6 months, is presently 3 months pregnant and is HIV positive. The couple was tested in Karnataka, then they came to Apollo and from there to our centre. We explained to them everything. The man understood, but the young woman seemed blank. Finally, we presented the pros and cons of taking Zidovudine to the young woman. The main question was: Do you want to continue the pregnancy and have the child? Their prime concern was that HIV/AIDS is fatal, an immoral disease and their first reaction was to have an abortion.

So we continued counselling them. The irony is that everyone knew except the young woman herself. The husband, his parents, brothers, sister-in-law knew about the couple's HIV status but the wife did not know. That afternoon they received the confirmatory results of the Western Blot Test. The woman knew she was positive and she decided she wanted to have her child - it was her first baby. The next morning, the woman came in with her parents. Her parents refused to allow her to have the child. This is the situation in India. Everyone knows before the patient himself/herself. Decisions of whether to have or not to have the child are often not

made by the person concerned, but by the whole family. This is our plight when we do counselling. Bearing this in mind, we should focus on the present situation in India before we start talking about universal testing for pregnant women.

There are 17 million people in the world dying of TB, diarrhoea, measles, malaria - diseases which are all curable. Here we are talking about something which is incurable.

More than half the number of pregnant women are anaemic. Can we give them Zidovudine if they are HIV positive? Do we need to do some more studies? Do we need to supplement with micro nutrients and vitamins?

800 million people lack access to health services. Half the number of women do not deliver in hospitals and this is backdrop against which we are trying to talk about policy in India for prenatal prevention (for prevention of prenatal mortality). Here again we see the paradox of the North and the South - the developed and the developing countries. 19% of infections are in the developing countries, 40% of women infected are below 25 years. So we have women in the prime reproductive age who are diagnosed as HIV positive. The first infection in India was reported in 1986. The whole country sat up and discussed at length and then forgot about it in the ensuing years. Later, the government started sentinel surveillance. In February 1995, 5 per 1000 were infected and within 2 years 21(2%) of the adult population was infected. There are 20 million live births a year. The low prevalence of HIV is 0.5 in certain states in India, while the high prevalence is 2.5%. So roughly there are about 5 lakhs ot women infected every year.

Presently, the transmission rate is as low as 26 with a high of 42. Roughly, about 2,10,000 children will be born with HIV per year. If this is our statistics, how do we prevent vertical transmission? If we follow the Thai regimen, which seems to be the most cost effective, the low cost will be about Rs.302 million and the high, Rs. 1680 million. These figures are just to prevent infection by Zidovudine alone.

It is a difficult situation because the standard of care in India is almost negligible. It is very difficult to compare this with the cost of treating a child who is born infected.

If we want to find the women who are HIV positive in the 20 million, we need to test. Roughly, it costs a dollar per test for ELISA in Chennai today. Now if we talk about pooling, we are doing 10 samples to a pool unlike 5 samples, it still would

cost Rs. 80 million to test the women who are pregnant and find those who are positive and then start them on Zidovudine. Next, we think of finding out if the child is positive. Usually we do a test after 18 months using ELISA, which will cost Rs. 40. There are other problems of feeding and immunisation. So if we want to know their status early, we need to do a PCR test, which will cost roughly Rs. 3000. These are the costs we are looking at if we are going to test antenatal women.

In Chennai, we have 3 major government-run hospitals. At the institute of Obstetrics and Gynaecology at Egmore, in 1997, there were 18302 new antenatal cases registered. At RSRM hospital in North Chennai, there were 27,000 new antenatal cases registered. So a total of 45000 women registered that year.

The culture in our country is such that when a woman gets pregnant (especially the first pregnancy), she goes away to her mother's house. So she may register in a hospital while she delivers in another. Some came in for the first time in labour. We have had patients who come at full term because they were refused delivery in private hospitals. They landed at our Centre in labour because they are HIV positive. These are the situations with which we are dealing.

At RSRM hospital in 1997, there were 90 new ANC cases on one day, out of which 10 were in the first trimester, 30 in the second and a majority of them were in the 3rd trimester and almost at the end of their pregnancy.

With this background, we have to see how we are going to counsel and test the registered people. Roughly, there are 90 women sitting at the outpatient department - we just cannot have one to one counselling. It is impossible, we will need so many counsellors, they need to be trained and can we afford it? So what can we do? We can do group counselling. May be every 10 women who come can be counselled in groups, show them videos and explain to them, and not do HIV counselling alone. We will have to do health counselling; talk to them about anemia, malaria and other things and add HIV to it. If the patients are not willing for an HIV test at the end of the study, we exclude them. We are not going to have placebos at all. Everyone who wants to get into the study will get the drug. For those who are willing to undergo the HIV test, we can do one counselling. Before we draw the samples, we need a written consent from them and then draw blood for the test. Once you get the samples, you can pool the samples if you want and do the test for HIV. If the women are found to be HIV negative, again you can do a

group counselling in the after noon or after 2-3 days, depending how fast your lab gives the test and if they are not in the window period and then they don't get into the study at all. But if they are in the window period, we have to repeat the testing. In my experience, girls get pregnant soon after they get married and they get infected at the same time. So when they come in the first trimester, they may still be negative. So we need to do a repeat test to make sure they are not in the window period, if they are HIV negative, they get excluded from the study. If the women turn out to be HIV positive then we do a post test counselling. If they opt for termination of pregnancy, we have to help them. Who decides that she has to have MTP, it is not just her (like I stated earlier), but her husband, her mother-in-law and everybody else. To go through with the pregnancy, we ask her to come in with her husband or her family. We include them in the study, get a written consent and test the husband. This would be possible for registered women who come within 30 weeks of pregnancy.

As part of the programme we have decided we would do 2 ELISA tests and 1 rapid test so that it is confirmed. The drug would be Vitamin A 25000 IU per week from the 2nd trimester, iron and folic acid starting from the 1st trimester, if they come in early enough. 100 mgms of Zidovudine in the morning and 3 tablets in the evening for 4 weeks as per the Thai regimen. For intra-partum, we do not have IV so we will give 300 mgms at the onset and 300 mgms every 3 hours. Now the problem arises if the registered woman does not come back to us and she goes somewhere else. She cannot say she is HIV positive and needs to take these drugs. The obstetrician may not deliver her. We will do caesarian sections elective, a week before the expected date, the baby will be tested at 48 hours to 2 months. At 2 months, the PCR test done for the baby would be ideal because they would come back for immunisation at that time. During the postnatal period, we do not give Zidovudine to the babies and we do not recommend breast-feeding. We would counsel the mother on the pros and cons of breast-feeding and leave the choice to her. Again, culture plays such an important role. If she does not breast-feed the child, everybody will want to know what is happening. So then, confidentiality is lost. We have to explain to her that if she decides not to breast-feed then we can help her with artificial feed. Help with formula feed would then be given in the first phase of the study. Can the government afford this on a large scale? Or is it only for the phase I study? Can you imagine 5,00,000 women having children and then trying to give them formula feeds? So we need to do research to find out how, in spite of breast-feeding, we can prevent infection.

There are a number of people who come unregistered at the last minute for delivery. How do we handle them? Again we will have to counsel the person and the husband or the family who accompanies and find out if they are willing to go through a test. If they don't consent, there is no test and they go through delivery. If they are HIV positive and are in labour, I thought the best would be either to give Zidovudine 600 mg stratum and then follow it up or Nevirapine, if it is available, which would definitely help to reduce transmission to the baby. If the woman is not due for another 2 weeks, than she joins the other group and gets the treatment like the others. This would be for unregistered mothers.

Cervical dysplasia or any STDs are some of the problems women who are pregnant have been facing.

I would like to say the first and most important strategy is that we need to learn and change our attitudes towards people with HIV. There was a young woman who delivered at a place 400 km. from Chennai. She had a second son. The family celebrated and then decided on a family planning operation. The obstetrician drew the sample of blood and the test for HIV came positive in the evening. When she was going to have the operation done, the doctor called the husband and told him his wife had AIDS. He was asked to remove her and the mattress, take her home and put her in a room because she had got AIDS (not even HIV) and that she was going to die. The husband took her home, grabbed the 2 children and neglected his wife. After 2-3 days, the lady developed very high fever and a very bad odour emanated from the room. Everyone said that the doctor was right, that she had AIDS and was going to die. Her parents were informed. Luckily for her, her brother who was a pharmacist, realised that the fever was due to puerperal infection. He put her in a taxi and drove her to Chennai. She came to our hospital. She smelled very bad and we found that the vaginal pack, which had been made after her delivery, had not been removed. It was infected with pus. We treated her and today 3 years later she is alive and well. So it is important before we talk about strategies and policies, to change the attitude of doctors who have to handle antenatal women.

14. PREVENTION OF HIV TRANSMISSION FROM MOTHERS TO INFANTS- STRATEGIES FOR INDIA IN THE CONTEXT OF CULTURE, ETHICS, ECONOMICS AND RESEARCH

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"Whenever a system is brought into play to copy with AIDS- be it a social, bio-medical research or medical care system - its deficiencies are exposed" (National Academy of Sciences, USA.1988)

India is one of the longest surviving among ancient cultures. The manner in which India confronts issues and problems of modern civilization must be understood in this context. As a nation we have not adjusted to the modern preoccupation with the pre-eminence of the individual's rights and the inflated monetary value of the individual's physical life. The 'philosophical' and the attitudinal reactions and responses to the entry and relentless spread of HIV and the devastation it causes in its path, in India and in many other nations, must be compared and contrasted with this understanding. Impatience and intolerance of the given situation and constant striving, almost rebellious, for change and progress, marks the way of "modern" culture. Patient acceptance of status quo and equanimity in suffering and loss, marks the way of the long surviving ancient civilization of Indian. Perhaps foolish in the shorts term but who knows, in the long term?

Throughout human history, change has been ushered in by individuals. The pattern of India's confrontation with the problems of the world is woven by strong-willed individuals who have found and shown new ways to cope with them. Always, not upsetting the applecart, but in keeping with the cultural ethos, and moving ever so slowly towards the modern.

So it is also with HIV and AIDS. By 1984-85, while so much attention was visible in the media all over the world, the leadership in health care, public health or medical research in India was going to give it no attention. One individual made the difference; in the private voluntary sector. So it is today: one person does the research to try to make treatment (to prevent mother to infant transmission) affordable; one person seeks to develop a national policy or guideline. The leaders,

mean while, have not taken the problem very seriously. So also, the problems of poverty, illiteracy, tuberculosis and primary health care.

The prevalence of HIV infections among pregnant women range from 1 (Kerala) to 40 (Mumbai, Pondicherry) per 1000. The obstetricians and pediatricians have been given no guidance to cope with this problem.

Ethics is a product of culture. Ethics of modern times demand autonomy to be respected, beneficence to be evident and justice to be ensured in medical interventions including research. Where persons willingly forgo autonomy in preference to heteronomy by the more knowledgeable and wise intermediaries in the choice of marriage partner, career, and medical treatment, how do we cope with the desire to respect autonomy of the individuals concerned?

Medical interventions are judged by cost-benefit ratios and cost-effectiveness analysis. Let us examine routine Hepatitis B immunisation, widely recognised to be extremely favourable in economic returns for the investment. At the current market price (in the private market: government ignores it) it will cost US$ 6 to immunise one child. Our per capita income is below US$ 400 per year. One and half per cent of GNP for one vaccine? So there is this element of "ability to pay" and "willingness to pay", which overrules cost-benefit and cost-effectiveness. The question of antiviral therapy to prevent (actually to reduce) the mother to baby transmission of HIV also needs to be evaluated not only by classical terms of economics, but also by affordability: either to the government or to the individual. Also by the willingness to pay.

In conducting research, essentially it is for the researcher to uphold the principles of ethics. Regulatory mechanisms are weak. Can one researcher ethically give an abbreviated course of antiviral therapy and measure the outcome without a double blind trial with the control arm getting the ACTG 076 protocol? Should we endorse the standard adopted in countries with GNP per capita of over US$20,000 or should we adopt the dictum: "Let not the perfect be the enemy of the good"?

Should we counsel every pregnant woman to choose screening for HIV infection? Can she choose with autonomy? Can we cope up with the consequences or do we leave it to her? Which is in her best interests, to know, and then know that she cannot cope, or not to know, so she does not have to cope until when the manifest problem is not her own, but shared by others in the family?

15. COMMUNITY'S RESPONSE IN THE SUCCESSFUL IMPLEMENTATION OF AN INTERVENTION STRATEGY TO PREVENT PERINATAL TRANSMISSION

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When we talk about HIV/AIDS in India, we are talking about a country of one billion people. Talking about achievements at the recent Olympics, we won one gold medal; in population we are second to one and in HIV/AIDS and tuberculosis, we are second to none.

In India, HIV spreads mainly through ignorance. I can give you a classic example. In a case study at our IHO-Wadia model, an HIV positive woman, when questioned, said that she did not have sex outside marriage. She explained that she had a pious husband, who put *tikka* on his forehead and could not possibly be having sex with anyone else. We asked her to bring her husband to meet us. When we spoke to him, he said that he did not have sex outside. I asked him who else lived at home besides his wife. He admitted that he had sex with the maidservant. We convinced him to bring the maidservant. During our discussion, she revealed that she could not have sex only with her boss. He would not take her to the movies, or to the garden. So she had befriended a taxi-driver. The taxi-driver had picked up the infection at Kamatipura and passed it on to the servant maid, the maid had infected the husband. The husband infected the wife. and the wife infected the child. All of them thought they were not at risk because they were not having sex outside the house and certainly not in the red light area. This ignorance has to be looked into.

It is not possible to do one to one counselling in our setting. Every day, there are 50-60 cases. But we have systematised the procedure. We divide people into groups of 15 and counsel them. We use two to three ways of informing them. Nobody is tested forcibly; they have an option of opting out from the test. The issues related to mother to child transmission, and paediatric HIV are not being highlighted. Nobody was willing to talk in the Assembly and the Parliament till we documented the first paediatric HIV case in August 1990. Only after that did they start working on it . So we need to document cases everywhere before we start to get attention. As we go on we should look at the pain being caused to children. Many people emotionally discuss what options are available for the infected chil-

dren whether children will be harmed and so on. But many children have already been infected. At the IHO-Wadia model or in the hospital, children are dying at an early age. Almost one third of their lives are spent in the hospitals. Sometimes both the parents are dead and the child is the liability of the hospital, the social workers or the nurses because there is no one to look after it.

This slide shows a child in the mother's womb. The child is asking every one if it has the right to be born as HIV free or as an HIV orphan? This kind of question had to be answered by every one. We in India have many activists. We have plain activists, animal activists, human rights activists but very few child activists because here the child does not cry. It is in the womb of the mother. We need to create an understanding among the people that we are fighting for somebody who is not yet out in the world.

We are still juggling statistics. We are debating about somewhere around 38000 HIV positive patients to 10 million HIV infections, In 1996 at Vancouver, Peter Plot said that India is the country with the highest number of HIV infections. Statistical jugglery is going on in India regarding the number of infected in India. There is a German saying: "Statistics do not make you laugh, figures do not make you cry". This human suffering. In Mumbai, however the prevalence of HIV infection in adults has stabilised. Whenever we want to decide on a policy for mother to child transmission prevention, we have to look at many issues, eg. the selection criteria. Who should be selected? If in India we have a policy of VDRL testing as a national policy to prevent mother to child transmission of syphilis, why can't we have a national policy on mother to child transmission prevention for HIV?

Our experts go to Thailand to look at models, they also go to Uganda, Kenya and even as far as Washington, to look at models but they haven't crossed the road to come to the Wadia Hospital. Obviously our experts do not want to look at indigenous models which have been developed at low cost in an integrated way. In selection, we have to decide on a policy that, come what may, we have to do the national screening of the mother. We know that there are many implications. Cure has to be integrated. Once you identify the positive people, they have to be cared for in the same atmosphere. So you have to create a battery of social workers, counsellors, paediatricians and gynaecologists to care for them in the given atmosphere. UNAIDS has been contemplating a policy that in developed countries, the mother should not breast-feed, but give formula feeds. But in the devel-

oping countries, they have asked the mother to breast-feed their babies as their babies might die of malnutrition: But your patient wants to reduce the transmission to the lowest possible. So where does UNAIDS come in the picture? So the UNAIDS guidelines for developing countries do not suffice here. Everybody talked about breast-feeding or no breast-feeding. Nobody talked about modified breast-feeding. You express the milk in a bowl, heat it and give it to the baby. Now we know that the HIV virus, when heated to 70°C for 10 minutes, will die. Since we know this property, we should devise a strategy to provide something like a breast pump which costs Rs.550, or manually express the milk, which is an alternative strategy.

Regarding the issue of orphans, some people question why a child of positive parents should be saved.It is going to die and even if the child is saved, it will be an orphan. This is debatable. Ultimately, it is the right of the child that has to be protected. We are not talking from the view of society. How cost effective is it to have HIV testing? In India, people talk of the all or none law. Either they should test everyone or test none. When they started testing in blood bank from 1989 till 1997, they were testing in urban centres free of charge. The blood banks were testing for Hepatitis B, malaria and VDRL at their own cost and recovering it later from the patients. For HIV, we are giving them free kits and they recover the cost from the patients too. At the same time, in many places, HIV testing is not done at all. Now they have decided that they will not provide kits. In HIV testing for the mother and the child, we need not test everyone directly. We can have pooled testing. This can reduce the cost, which can come down to Rs. 10 for the mother. Regarding counselling and care, we need not create a battery of vertical who will work as only HIV counsellors. We need to integrate the care into the existing system. Almost all the medical colleges and their hospitals have social workers. There are a few counsellors too. We can train and teach them. Similarly, the doctors also could be trained in counselling. Discrimination is a state of mind. People say that when we find someone is positive, he or she will be discriminated. People who discriminate will do it even if they are sent to heaven. In the Wadia model, the positive people are given better care. We give them the options of various drug regimens. If they cannot afford the medicines, we provide them with medicines. Most of the pregnant women in India come to the clinic late in pregnancy. We need to educate the women that they should start coming to ANC clinics early in pregnancy. Obstetricians should offer HIV testing along with the pregnancy test. They do not have to wait till the pregnancy progresses further. Only 5% of patients

can afford HAART therapy. These patients can be on therapy and become pregnant. With a lower viral load, there will be lesser chances of transmission. On one hand we say that we cannot afford the HIV test but on the other hand we have to do the viral load. We also have to look at opportunistic infections. We need to devise some strategies where we can evolve and fulfill all the ethical criteria and still provide better care to women. For confidentiality too, we need to devise some strategy, in the Wadia model, we use locally available Zidovudine. The cost is only one third of the international cost. We also do elective Caesarian section. Our results are much better even though we are not able to give intravenous Zidovudine during labour. So even in comparison with Thailand, to save a child in the Wadia model will cost $600 which makes it one of the most cost-effective models.

In 1990 I said that India would top the AIDS list in this decade. And this was achieved in a record 5 years . So what is it that we need to look for in the future. Nobody is talking of the orphans or health care centres for the patients of HIV/AIDS. In the entire NACO programme, this is a weak aspect, which they now want to develop. To inform our patients, we have developed 3 strategies in our out-patient clinic. There are a series of posters kept in 2 or 3 local languages that they can read. There is literature available in the local languages. We also have group meetings. Only after a patient is found positive do we go in to proper pre-test counselling, couple counselling and post-test counselling. We talk about community involvement. In this, it is very important to involve religious programmes, religious ceremonies and religious leaders, (which is the weakness in our national programme). The Wadia model is replicable. It is indigenous and cost-effective. It can be practiced in any medical college and it is a practical model.

RECOMMENDATIONS

RECOMMENDATIONS
GROUP I

INTERVENTION STRATEGIES FOR INDIA

CHAIRPERSONS
Dr. Alka Deshpande, Mumbai
Dr. Shanmuga Priya, Chennai

Less than 500 newly infected infants are born every year in the developed countries as against more than 1000 newly infected children seen every day in developing countries. In addition, 25 million deliveries are taking place every year in India. With the progressing HIV epidemic in India, this is the time we have to address ourselves about the issue of mother to child transmission. We have seen from our epidemiology data that the HIV transmission between male and female has come to 1 to 1 and therefore we expect a large number of seropositive pregnant mothers presenting with pregnancy-related problems.

- When we talk about intervention strategies for decreasing HIV mother to child transmission, we have to educate our community and make them aware of this problem. We have to use all our methods and means to bring about awareness in the society, so that HIV positive men can bring their pregnant women for counselling and treatment. There should be a general sensitisation about intervention strategies and therefore we must undertake programmes to bring about awareness.

- The HIV epidemic in India is 12 years old and there are a lot of reservations and apprehensions on the part of health care workers. By health care workers, I mean all those who deliver health, right from doctors to class III and class IV workers and paramedical staff. We must give them training. Training is not a one-time programme. It is a continuous process of training so that we can update knowledge. In addition to updating, what we require is to bring about an attitudinal change in the medical fraternity. It is mainly because of attitude that most HIV patients are not getting the care that is expected or anticipated. All HCWs should have hands on experience. It is no use giving them theory lectures alone. They must go out to the institutions where care is provided, where caesarian sections are performed, and where surgeries are

done on HIV infected individuals. In this way confidence can be built up in HCWs.

- It is good to have counsellors. It is very difficult considering our resource constraints, that we have a separate category of counsellors. If they are available, it is most welcome. As the Indian psyche goes, most patients have faith and a good rapport with health care providers, particularly doctors. Therefore doctors should be sensitised in counselling techniques and they are urged to spend a little more time with their patients. So training of HCWs to update their knowledge, to bring about attitudinal changes, to give them hands on experience and to sensitise them in counselling techniques is essential.

- There is always a dichotomy between the public sector and the private sector. This country would sooner or later need a law to make the private sector accept HIV patients without any discrimination. Previously, the private sector did not accept any medico-legal cases but after a law was initiated, they have started to accept medico-legal cases. At least they are obliged to give first aid to any medico-legal problems before the patient is referred to a tertiary care centre. We need a law without which it is very difficult to bring the private sector to accept HIV infected cases. This is generalisation. There are exceptions in the private sector which do good work.

- Now we come to the question of sensitisation till the law is promulgated. We have to go by our policy of persuasiveness. We have to persuade them and therefore we have to sensitise them to these problems. And we have to inculcate confidence in them so that they can handle all HIV patients without discrimination and without an HIV phobia. For this, we need pressure groups not only in the medical field but the pressure groups should come more from patients and the NGOs and the families of the infected.

- These intervention strategies are tried all over the world with the help of UNAIDS, CDC, WHO and so on. As vertical transmission has been increasing in those countries, many studies have been conducted. They have proved their safety and efficacy. Learning from their successful experience, we thought we should not deprive our infected pregnant mothers from therapeutic interventions which are available. Any infected pregnant mother who comes to us should be offered counselling. The counselling should be offered to women, husbands or their sex partners or the father of the children. If the

need arises, we should offer counselling to the immediate family. This is the first step of the interventional strategy. Then comes pharmacological intervention, which has been proved safe and efficacious. And with this successful experience we should learn and we should offer this intervention in 2 parts. The first is the service part. All infected mothers who are sero-positive should be offered this intervention as a service. The second component is the research component. In the service part, as you all know, there is the well-documented ACTG-076 programme which requires the patients to take AZT for long time, starting from the early period of pregnancy, then intra-partum, postpartum and then the child also has to be given AZT. As against the ACTG-076 strategy, there is the Thai design. With the ACTG-076 programme, vertical transmission is reduced by 67% while with the Thai design, the vertical transmission is reduced by 50%. There is not much of a difference. The Thailand design suits our country or any developing country with resource constraints. Therefore, the Thai design will be more suitable to India. UNAIDS's latest guidelines were announced on Oct. 9th 1998. As far as these guidelines are concerned, the standard protocol should be practised and should be made available as a service to infected mothers - 300 mgms of AZT orally - twice a day (bid) from the 36th week till labour; the intra- partum AZT 300 mgms orally, 3 hourly, limited to 3 doses. That means the duration of labour should be around 9 hours (maximum time). The Thai design also advocates vaginal delivery. We discussed vaginal virucides and the group did not recommend the use of vaginal virucides like chlorhexidine and others.

There is no treatment in the postpartum period for the mother nor for the infant. In this design, a warm wash given to the newborn so that all the secretions should be washed off. In the Thai design and UNAIDS recommendation, the infant should not be breast-fed.

Next comes that question of immunisation of the newborn. At this point, we do not know the infected status of the newborn. As a service component, we advocate an immunisation programme as per the WHO protocol, so we should give polio, DPT and other vaccinations. This is included as a service component.

During antenatal care, they should be supplemented with folio acid, iron, zinc and multi-vitamins. There was a lot of discussion on premature rupture of membranes. I recall a paper from the Institute of Research in Reproduction where they showed

that 47% of our normal (HIV negative) women have very poor genital hygiene and infections are prevalent in them. They have either trichomoniasis, Candida and human papilloma virus. Therefore, in general, we should look out for genital hygiene in the antenatal period so that no infection is missed. Proper treatment should be instituted promptly, so that bacterial infections contributing to the premature rupture of membranes can be avoided.

In research component - it has many areas. As we talk of the Thai design, we have to see how far it will be successful and feasible in our country. Some of the research areas we highlighted are:

- We should identify centres that can carry out proper research studies. There should also be no duplication of the work. Because of our limited resources we should identify the centres of research work which should be systematic and well designed.

- We should have research in optimising the dose of AZT in our population. But right now, we accepted UNAIDS recommended doses.

- Another area we should study are other anti-retroviral drugs. There are many study protocols and projects which are being conducted where they give combination therapy AZT + 3Tc or DDI.

- Research in single use of Nevirapine.

- With the availability of more and more drugs in our market, many people will be taking up triple drug therapy, if a lady on a three-drug therapy conceives, then it will be a good opportunity to study the pharmacokinetics of anti-retroviral drugs during pregnancy.

- It will be worthwhile to have a comparative study with AZT intervention with vaginal delivery versus the elective caesarian section. When we talk of elective caesarian section, it brings in the training component of obstetricians and the other paramedical workers.

- We also considered the pros and cons of breast-feeding. We thought this would be a good research area considering the prevalent infections in our country. The morbidity and mortality study with and without breast-feeding in the people who are receiving AZT interventions need to be studied.

In the service design we did not consider studying the HIV infection status of the newborn. This is a good area of research and therefore we advocate RTPCR, qualitative PCR to know if the newborn is infected or not and therefore we need to do RTPCR at 0, 48 hours, 3 months, 6 months and 18 months. This is the standard protocol. Considering our limitations we could try and find out whether we can do RTPCR at 48 hours, 3 months, and 6 months and the antibody test could be done at 18 months.

If you do not know the HIV status of the newborn, the developed world advocates that BCG vaccination should be delayed. So also the polio vaccine. OPV should not be given to an HIV infected child. This could be another research area. We advocate and recommend all immunisation schedules to be carried as a research study. Today, an injectable polio vaccine is not available in this country but if the killed vaccine becomes available, we should find out the beneficial effects of the same.

We need long term follow up of infected mothers as well as long term follow up of children born out of these intervention programmes.

Supportive care outcome - when we are giving supportive care of iron, zinc, multivitamins, that will be another area of research. What will be the effect if it brings down the morbidity of the infected?

We talk all the time about the feasibility of studies in the public and private sector but are we giving them the protocol? Is it feasible to carry them out in the private sector? In the private sectors, there are doctors who are willing to implement these programmes but the hurdles are from the management. They have their own reasons and therefore it will be useful to look into the feasibility of implementing these intervention strategies in the private sector as well.

Social aspects - It will be useful to find out what happens when a pregnant mother is detected to be HIV positive. How will her husband and her family members treat her? What are her social problems? We know certain women who have been nancy, because there is a history of blood transfusion. What social support will these pregnant mothers get? This will be a very interesting study.

Alternative systems of medicine - This is a questionable area because when we talk about alternative systems of medicine, they are tried by the patients. The people

voluntarily go to them out of despair, or they feel helpless and therefore they go on trying these alternative systems. At this point of time, we cannot scientifically advocate that alternative systems be tried by the pregnant mother considering the fact that we do not have any data about the teratogenicity, mutagenicity or carcinogenesis of the drugs used in alternative systems. There was a suggestion if a lady is already taking these medicines and has been feeling better with them and if she were to conceive, then we can look into it and get basic data on the usefulness of these drugs in HIV infection.

We should not treat AIDS patients as untouchables. This should be integrated into all our programmes. We cannot see AIDS in isolation. It encompasses all the disciplines of medicine and therefore it has to be integrated with all other programmes. A vertical transmission programme has to be integrated with AIDS control programmes and reproductive health programmes.

Normalisation of the process comes automatically, when the number of patients goes on increasing. There is no escape; we cannot run away from the patients. Naturally we have to accept and that will bring in normalisation. Initially the family physicians in Mumbai were very reluctant to examine HIV infected patients. The same was true of the consultant. But slowly all of them have started accepting and giving treatment for these people. So it is possible to achieve normalisation.

RECOMMENDATIONS
GROUP 2

HIV TESTING AND COUNSELLING

CHAIRPERSONS
Dr. I.S. Gilada, Mumbai
Dr. Sheila Shyamprasad, Chennai

- Testing for antenatal women should be mandatory in view of the fact that vertical transmission can be decreased if detected.
- The test should be incorporated along with other routine tests.
- Counselling in the form of IEC material/pamphlets/poster/group counselling should be done prior to testing.
- An option to opt out of the scheme should be available: in such cases there is a second opportunity to counsel.
- Cost of testing can be brought down by pooling samples.
- If the patient is a positive individual, counselling on one to one basis should be undertaken. The passive partner notification now comes in - the wife is requested to bring her husband for counselling. This is followed by couple counselling and thereafter family counselling.
- Total confidentiality to be ensured.
- The couple can be offered (a) MTP if >weeks, (b) <20 weeks - the Thai protocol as per UNAIDS recommendation.

RECOMMENDATIONS
GROUP 3

COMMUNITY PARTICIPATION IN PLANNING AND IMPLEMENTATION

CHAIRPERSONS
Dr. Jayaprakash Muliyil, Vellore
Dr. K.E. Bharucha, Mumbai

We were fortunate to have in our group some members, who were working at the grass root level, especially people with HIV and people with different sexual orientations. They brought in a fresh perspective into the group dynamics.

Why do we need community participation? What is wrong with what is happening today? There is a big divide between the health system and the community out there. This division is much more conspicuous when we consider certain marginalised communities, which are at a higher risk of contracting HIV. In many areas people do not follow allopathic systems or go to government hospitals for STD treatment. They go to what we call 'quacks' and get treated. Quacks are unqualified doctors, but for some reason they empathise much better and are less judgmental. I think this fact is well known in the group. One person said the Siddha (traditional systems of medicine) doctors are more understanding. "They talk a language that we understand and it is much more comfortable to sit and share our problems with them than your modern medicine." Most health professionals are naive with respect to sexual orientation other than heterosexual contact, especially in India. And people do not know how to-deal with such situations. One person talked of his personal experience, "When I talk about my sexual orientation the doctors look confused, they look at me with revulsion. Then how do you expect me to go and share my problem with them?" In other words in these areas, our doctors are incapable of handling such situations.

Health systems, by and large, which we have designed are like one-way traffic. We send the vaccines to the village, we send the ORS there. There is no feedback from there. We pay a lot of lip service to counselling. But what really happens is that patients get a very lengthy lecture and are sent off. That is how counselling very often turns out to be.

The group was of the opinion that we need to approach the issue scientifically. People with skills in community organisation will be ideally suited for this purpose. Needless to say the process will start by creating awareness in all the subsects of the population regarding these problems.

- The community should be able to appreciate the problems of HIV in the context of its socio-economic situation and general health status in order to ascribe proper priority.

- It should be aware of the contribution the health system can make in reducing the risk of infection, for example, the role of the drugs in reducing the transmission from mother to child.

- The health system should be able to respond to the priorities of the community and be able to tailor the programme according to the needs and convenience of the community.

- Marginalised groups should be able to play an important role in programme planning, implementation and evaluation. Members of those groups should be seen as resource persons in our fight against HIV. Programmes need to include not only the health systems but also the educational system, the law system, enforcement authority and the social welfare department. The comprehensive programme against HIV should also ensure that the component of support to HIV affected individuals is given due importance. This will help in reducing the stigma against HIV.

Since the magnitude of the problem varies from place to place, we recommend the exact shape of the programme be permitted to evolve through local planning. Our aim should be to create an acceptable, accessible and affordable programme which can create an impact on the HIV disease scenario.

RECOMMENDATIONS
GROUP 4

POLICY ON BREAST-FEEDING

CHAIRPERSONS
Dr. Wendy Holmes, Australia
Dr. P. Manorama, Chennai

It is important to recognize that breast-feeding is essential for child health in India and should continue to be protected, promoted and supported. We should call for increased resources for measures such as baby friendly hospital initiative and community education, to promote breast-feeding because of the increased threat to breast-feeding rates.

Certain things are necessary to implement, a policy of avoidance of breast-feeding, for women identified as HIV positive. These are:

- access to antenatal care;
- routine offer of testing of HIV with pre and post test counselling;
- training doctors and health care workers;
- family planning service availability;
- community education; and
- family counselling and support availability.

Criteria developed for deciding which women are eligible for Government assistance with replacement feeding:

- information materials for mothers and families;
- training of mothers in preparation and cup feeding of replacement feeds; and
- Good Child health care services.

If these things are not in place, the policy will do more harm than good.

- More babies will die from absence of breast-feeding.
- Mothers will be discriminated against by family and community, causing emotional distress and rejection.
- More babies may he born infected, without the spacing provided by breast-feeding.

- Women menstruate straight after delivery.
- Increased risk of sexually transmitted diseases.

CONCLUSION

Need to implement the policy continuously and in stages.

- First undertake research to obtain necessary information

METHODS

Qualitative: group discussions and in-depth interviews with women in different states.

- rural and urban,
- poor and wealthy,
- positive women,
- pregnant women,
- mothers-in-law and
- men

Quantitative: KAPB study. Questionnaire based on qualitative result. In pre-test questionnaire, ask about attitude to testing, to positive women, to breast-feeding. Pay attention to effects of this research.

Operational research	Especially
Alternative to breast-feeding	Heated EBM (Expressed Breast Milk)
How acceptable? Affordable?	Milk banks
Available? Safe? Feasible?	

Individual women

Women's attitude to breast-feeding and cup feeding

- Explore possibilities for developing structures in rural areas so that women have access to this intervention.
- Develop education and information materials and test them.
- Organise training courses for health professional at all levels including counselling and care-taking.

- Identify suitable NGOs for partnerships between hospitals and NGOs.

Implement policy in stages

- In selected city institutions such as medical colleges and hospitals which have the necessary infrastructure for screening care and support.

- Selecting rural areas to explore practical options so that rural women can benefit from the policy.

Document the process of implementation. Involve all players in participatory evaluation

- Professionals, women and families.
- Also follow up on babies to check impact on morbidity and mortality.

Review of progress and recommendation and expansion of intervention

Suggested timeline: Research -2 years, first stage of implementation: 2 years.

It is important to remember that transmission through breast-feeding when the woman is infected after delivery is a very significant route of transmission.

The policy needs to include a community education campaign aimed to include men and to appeal to their sense of responsibility and protection of their children so that they are less likely to have sex outside marriage. If they do, they will be more likely to use condoms.

Community Education: Emphasise transmission from mother to child, but there is no need to mention breast-feeding. It will increase child mortality. Get the media to report this issue carefully, so as not to damage breast-feeding rates.

RECOMMENDATIONS
GROUP 5

EFFECTIVE AND SAFE STRATEGY (IF AVAILABLE) TO BE INTEGRATED INTO PUBLIC HEALTH STRUCTURE - HOW?

CHAIRPERSONS
Dr. T. Jacob John, Vellore
Dr. Sankaran, Chennai

The strategy involves

- Training of the personnel in health mainly the medical as well as the paramedical. To quote an example, any training programme should have a standard model that was followed by the expanded programme of immunisation. So, the message what is said from one and all should reach the beneficiary in a uniform way and not in a different way. Not only is training important, as days pass, changes occur in the advancement. So in addition to training, re-orientation - Continuing Medical Education (CME) is very essential for updating knowledge both for the teachers as well as the beneficiaries.

- Standard guidelines to be made available, specifically in the local languages so that we train paramedical people which will be very useful and should be available not only in English but also in the local languages.

- Development of infrastructure. For any programme to succeed, the infrastructure facility should be made available in a strong base. Even in some teaching and budding institutions, there are no proper paramedical laboratory facilities. In our country, we should have an established and trained technician in every microbiological laboratory. Not only for HIV but also for common problems like investigation of blood cultures, blood widal and urine culture in addition to HIV testing. With regard to teaching institutions, medical colleges and government headquarter hospitals, we would like to involve non-governmental organisations not only in financial assisting but also in educating and involving the public. In our group we had a difference of opinion to start with -on whether to have non-governmental organisations at whatever level - be it at the primary health centre level or Taluk level or headquarters level. Finally the group decided to have it at the teaching level, city level or headquarters level so that there would be no intervention by non-government

organisations. So our group says to insist in the primary health centre level only the IEC activities and health education activities. It has to he done either by the VHN or the-public health nurse or any other available staff at the Primary Health Centre (PHC) as they could impart health education in relation to HIV to the mother or the husband or the family members who accompany the pregnant woman. Another discussion was about when to have counselling and at what level it was to be done. Whether to have it at a group level or individual level, we leave it to the strength of the total population. At the medical college level, you can have counselling at the group level with the help of a social worker who is already available at all medical college institutions. So we need not appoint and have an extra expenditure in the form of a counsellor. Access to the central laboratory and any other laboratory facility is necessary to check the test results or cross check these results. As you are aware, in some labs, they say he's HIV positive, we are not sure what method was followed, whether the diagnosis was right or a false positive. Again it is an agony to the mother as well as the whole family.

As you are aware of all the referable services available, I was an ICDC medical officer long back to start with. Our group also agrees that referrals, as far as the ICDS is concerned, it is only the record, practically it did not work out. So to have referral services, it should be made functional. When patients are referred from an institution or from a primary health centre to a taluk or taluk to an institution, the mother or the father of the family has to forego their earnings for that day. So it should be compensated or it should be made available in some other form. In this way, all the cases which were referred by the institution goes back to the referral institution and in the same sense they should also have a feedback. In teaching institutions, we should have a specific medical officer. Or a responsible person who has to see the referral system, so that he can give the feedback to the concerned medical officer. They are not given any priority and with the referral card system, the patients referred should get the priority and can be seen by a specific doctor or person and feedback should be given to the PHC or taluk hospital.

As government doctors, we should give routine care for HIV positive patients, but our group recommends clear government guidelines for HIV positive patients. One of our members stated that when a HIV positive woman in labour went to a private nursing home, they demanded Rs. 25,000 to Rs. 50,000 for doing a caesarian section. The answer to this has to be decided by the group.

Safety of the health personnel:

Health personnel can be given some additional allowances or extra income when they are involved in occupational hazards. There could be an insurance scheme for people in the vulnerable group, that is, medical or the paramedical staff. They could have group insurance.

As far as the finances are concerned, the health budget is very low in our setup. We have initiated cost recovery schemes. For example, when competing with private nursing homes they can have all the investigations. If they take an X-ray, they can collect charges of Rs.10-20 and X-ray can be given to the patient. That is being done in some of the government hospitals even now. But they don't charge for the X-ray but when the patient wants it, it can be given at the cost of Rs. 20.

In our institution in Trichy, they do a CT scan in the outpatient department at a cost of Rs. 550. So some cost recovery schemes compared to the private can be given some concession, so that it is an income for the Government.

At some pioneering institutes like Chennai Medical College, they have comprehensive health checkup schemes. This is an additional income for the government.

As far as treatment is concerned, we got these drugs which should be included in the essential list of the drugs as per the Government norms and State Government. That should be made essential and should be made available locally throughout the year.

RECOMMENDATIONS
GROUP 6

LABORATORY SERVICES

CHAIRPERSONS
Dr. Elizabeth Dax, Australia
Dr. Dorothy Bray, United Kingdom

We were very fortunate to have facilitators from 3 different countries and also participants belonging to different state of the country. It has made our work much easier as we had an overall view of what is happening as far as laboratory services are concerned all over the country.

The recommendations are as follows:

- Quality assurance of HIV testing: This is important because the technical know-how of the laboratory staff leaves much to be desired as it stands. So there should be training programmes which includes CME. and also the management of laboratories has to be incorporated into these training programmes.

- The establishment of referral laboratories, which I think are already in existence, probably very few are actively functional. We could have more functional referral labs in different parts of the country to take care of the quality assurance.

- The need for uniform certification or licensing process for establishment of laboratories. This is very essential. Though there might be laws to guide the establishment of laboratories, they not being put to use.

- Adequate supply of suitable diagnostic kits and equipment: This was a suggestion, because most of us who have these laboratories do not have access to diagnostic kits. Government supply is very meagre. Maintenance of equipment and purchase of equipment is out ot the reach of most institutions. This also includes adequate supply of reagents and adequately trained personnel to manage these labs.

- Probabilities of evaluating new testing strategies e.g. the pooling of samples as the other speakers have mentioned. Pooling is in relation to testing.

- Uniform application of WHO recommendations of HIV testing strategy : This has to be implemented in laboratories all over as the personnel are still not very aware of what the WHO recommendations of testing strategies are.

- Diversification of test was another recommendation. We have to look into the cost effectiveness of testing and supply of test kits.

- Recommendation of HIV testing in relation to vertical transmission. We were of the opinion that there should be HIV testing for all pregnant women.

- Maintenance of confidentiality has to he ensured so that we can be sure that we get more and more women to be included in the programme. We have to couple this testing with counselling for all women which can be group counselling, which has already been mentioned, and possibly include them in the testing during their first visit itself. And the tests have to be repeated when necessary depending on the results of the first test and also on the discretion of the health care provider.

- Diagnosis of HIV infection in infants: We recommended testing of children born to HIV positive mothers. The timing of the test should be after 2 months by the RTPCR method and by antibody test at 18 months as the former is not easily accessible to most of us. We also have to consider and evaluate new-strategies for testing. For example. Dr. Elizabeth Dax has mentioned we could use the filter paper technique and other methods. Therefore we have to evaluate other systems too.

CLOSING CEREMONY

CLOSING CEREMONY

Arthur Ammann

Many people have spoken not only from their scientific minds but also from their emotions, from their hearts, from their experiences. Let me see if I can add some perspective. I leave you here with some assurance that you can accomplish things and make progress. We brought out many things that can overwhelm a practitioner, a patient, and government organisations. But I believe progress can be made and you have demonstrated it at this meeting itself. At most meetings that we attend in the scientific arena, we sit and listen about what we know and sometimes with some new information. You have been participants both by listening and by making suggestions. It was a different kind of meeting. You discussed not only what we know, what must be done, in the sense, whether or not you realise it yourself now, when you leave this meeting, there is another responsibility that you have assumed; and that is how can we accomplish the many things that we have discussed. And unless we assume some of that responsibility, we cannot say that this meeting is truly successful. So the success of the meeting will very much be judged by what happens from the time you leave this room. And I believe it will be a success. It may not happen as quickly as many of us want. It may not happen quite the way that we want. But some of those issues have already been mentioned. We have to collaborate, this is not something we can do independently and you have collaborated by sharing not only your success and some of your failures and some of the difficulties that you have encountered. We must be honest with one another in terms of how to move forward and how to succeed. We have addressed some very critical areas. The failure, I believe, of the international community to recognize the problem in India is a problem for India and them. That is not to lay blame on any one person or any one group. We must change that. We must say that this indeed is an international problem, we have to address the international issues. Then we have to bring to this country not only from the outside world an awareness of what the problem is, but also within the country. Without that awareness you will not be able to change what desperately needs to be changed You talked about HIV testing and I really feel that we are at a point in HIV testing where we have to change the door that people enter. In the past, the HIV test was to enter the door of discrimination, of loss, of hope and of despair. And we must change that door so that when an HIV test is done, it is not to discriminate but it is to offer the patient prevention, treatment and hope that there is a community that cares. And as dangerous as it may seem to many of us to increase the pressure on testing and how we test, I believe that it is one way to make people aware of what the needs of one individual are, and which the country needs to acknowledge. So we need to move ahead in our scientific knowledge, we need bet-

ter ways to communicate because we are not talking to one another, we are talking to the media. They must help us and assist us to disseminate the knowledge that we need and bring to us the additional resources, the additional individuals, that can help us to move forward in controlling this epidemic. What I realize in the United States, as much criticism as there has been about the activism and the advocacy that AIDS has brought, some of it is from envy because it is a success story. It is a story of a community becoming concerned about their disease, of the people who are infected, involving the scientists, the physicians and eventually the government. And now that model of success is being replicated in the developed world by the sufferers of other diseases who want to use the same model. And that, to me, is a success story in itself, and that's what we would like here in India to happen. What you do will affect not only the health care of HIV infected individuals but assist in the healthcare of all people. HIV/AIDS brings out all the problems that we encounter in the other areas - discrimination, gender issues, individual rights, human rights issues, poverty and economic discrepancies. And so as you move forward in HIV/AIDS you need to also keep in mind that you are moving forward in these areas and bringing these to the attention of the individuals and there will be progress. I too believe, as has been said here, that there is a need to integrate the care, so that we not only bring benefits to people who are infected by HIV/AIDS but we bring benefits of the increased awareness of the desperate need that health care has to be delivered to all individuals.

It is up to you all to implement these recommendations. I would not minimise their impact. I think our experience tells us that when a body like this, of interested people come together with their consensus and recommendations, the people need to pay attention to it. They can disagree with them, they need them to push for improvement. I fully agree with dissemination through publications as you mentioned. Put it on the World Wide Web, get it to your patients so that your patients understand what their rights are, what kind of health care they need. Give it to the government organisations, give it to NGOs. We can take it, we can publish it in the US and some of the American journals and have it as an Indian recommendation of what needs to be done in perinatal transmission of HIV. It doesn't have to be the perfect document nor does it have to be the perfect solution. But it should be a document and a method of moving things forward and keeping the pressure up and saying that we can do better and keep moving towards goals of improvement.

CLOSING CEREMONY

Dr. Jacob John, Vellore

It was extremely thoughtful on the part this University to have organised a very focussed meeting of a firmly unfounded group that has come up with very interesting recommendations. The problems belong to the community. The solutions also belong to the community. Our role as university and professionals is to define the problems and identify options and solutions and make choices available to the community. Only 25% of the women deliver in institutions, so there goes your mandatory testing. Unless the infrastructure is robust enough to absorb HIV specific solution, it will not succeed. In order to establish HIV testing, we need a background culture, microbiological testing, training, maintenance of equipment, understanding the variations of test, quality control, quality assurance, reference laboratories. These should be available not only for HIV but also for other infectious diseases particularly in the question of HIV opportunistic infections and on that infrastructure only will we be able to establish HIV diagnosis. Simply by sending an ELISA reader and kits to a particular institution, that being the only test being done, is not going to work. Doctor-patient communication has to be reexamined by the University, by the teachers, by medical schools. A certain amount of regulation and discipline has come to replace the anarchy situation that HIV has thrown up in our midst. These are the issues that have come up. I do hope that the document that the V.C. has promised will put clarity of thought into the aspects that I highlighted.

CLOSING CEREMONY

Dr. Alka Deshpande, Mumbai

We have been here for the last 2 days. Everybody says that India will have the largest number of HIV cases by the year 2000 and 2000 is only 13 months away. I remember the sentence spoken by Dr. Ammann-that India and China were hardly mentioned at the 12th World AIDS Congress. It was a very painful experience for us who attended the conference. And when we tried to interact, many people were willing to collaborate, but there are certain hurdles and some blocks. And the reason they told me was bilateral political issues. But I think we should introspect ourselves. We know it is going to be a mammoth problem and every one of us is making an effort in the best possible way and putting up the best capability to face this challenge. And still we have not formed a very adhesive force and we lack interaction. We have failed to project ourselves. Dr. Samuel and the University have given us a chance to come together to share our experiences, to share our views, to interact. They also organised some experienced faculty. Therefore it was a very good session for updating and interaction.

CLOSING CEREMONY

Wendy Holmes, Australia

It has been a very great privilege for me to be able to be at this meeting. And I have really learnt such a lot from being here. It is so important to remember the possibility of harm and the need to be cautious with the implementation of these interventions. The enthusiasm to prevent any mother to child transmission is a wonderful thing but we have to be careful not to do any harm. There is a real need for community consultation and research first, especially in relation to issues of counselling, informed consent, stigma and replacement feeding. It is very important that it be a staged implementation with review all along the way to see what the impact has been. We should not forget other initiatives such as to improve the status of the women in whatever way we can. Pushing for more resources in antenatal care, pushing for community education and pushing for identification and treatment of STDs and TB, all of those are going to do much more on a national scale to reduce the mother to child transmission of HIV. And they are also important in their own right.

In this world now, it is so difficult to get funding both for implementation of interventions and for research. The developing and developed countries are being invited to approach the private sector to get funding. We have to be careful when we approach funding and how interested the funding company will be. I am thinking now of infant formula manufacturers as a source of funding for research, and replacement feeding is a problem. Thank you very much. I have really learnt a lot here.

CLOSING CEREMONY

Dr. Uma Dethan, Kerala

In Thirukural, there is a saying that knowledge is like wealth but wealth, if you give it out, it will diminish but knowledge will increase. In the last 2 days we saw and we heard lot of experiences from experts all over the globe. All the deliberations I am sure, you will be able to implement. Nothing is impossible. I thank our VC and the Department of Experimental Medicine for organising this conference. The decision taken to publish the Proceedings is an excellent one. The Proceedings are going to be the guidelines for effective interventions in the mother to child transmission of this great menace.

CLOSING CEREMONY

K.N. Chandrasekaran, Mumbai

I congratulate Dr. Samuel and his team for putting through a wonderful workshop. Glaxo Wellcome will be an integral part of your fight against AIDS and prevention of mother to child transmission. We stand committed to bring all the products of Glaxo Wellcome to our country at Indian prices. We have a lot of information to share and we are pleased to do that. Let us jointly fight this menace.

CLOSING CEREMONY

Dr. Bannerjee, Calcutta

Since 1993, working in the field of HIV/AIDS I have not been able to join in any programme where anyone can assemble physicians, obstetricians, STD specialists, medical administrators and educators. In the last 5 years, NACO has failed to do what MGR Medical University has done. I am thankful to the VC and Dr. Samuel for organising such an innovative, purposeful workshop in the city of Chennai. Regarding organisational aspects, everything went on like a well-oiled machine. There was no gap. At no time did I have to call someone for something. Regarding the academic content, definitely it was focussed among the people who matter in the academy of this particular topic. But time is very short. There could have been some space for more interactions, as India is one where regional universities are many and the cultural diversity is also wide. So more scope for interaction between the people who are involved in HIV/ AIDS could have been there.

Objective

Is it the objective to make some comments and recommendations to the Government. (Should you see a technocrat doing anything according to his wishs and this is the state of matter that is going on in all our vertical programmes.) Also in AIDS, the technocrats think they know best. Should we exert ourselves? Should we say to our planners, our policy makers that it is the technical people who are going to give you advice on these technical matters and not the brokers who might be going to some training course to some world finance like the World Bank. Who understand best our problems ? Is it the World Bank ? Or is it the peole who are working in the HIV/AIDS field day to day? It is we who have to decide and exert our right in the right place and at the right time. I do not know whether these recommendations are going to be implemented. But now I am more enlightened, more experienced and more committed to my HIV/AIDS patients.

CLOSING CEREMONY

Dr. Mohammed Kutty, Kerala

This conference is unique for me as from our state of Kerala, 9 people have come. The leader of our group (Director of Medical Education) was present throughout the conference. AIDS is an international hazard. If its going to be teamwork, then only can we achieve health for all by 2000 AD. AIDS is a behavioral problem. Now we have to practice what we preached here, that too at the grass root level. I have learnt so many things from the experts here.

CLOSING CEREMONY

Dr. Rajendran, Chennai

I congratulate the VC and his team for conducting this conference. As far as Tamil Nadu is concerned, the first HIV case in India was reported from TN, the first AIDS society was formed in TN in 1994. Awareness of AIDS and the first behavior surveillance was conducted in TN. The largest number of blood samples was screened in Tamil Nadu. We could also be the first in stopping vertical transmission. We are very eager to get the official document from the Tamil Nadu Dr. MGR Medical University so that we can go ahead with the programme.

CLOSING CEREMONY

Dr. (Major) D. Raja
Vice-Chancellor

I am very happy today because we have conducted a useful Round Table Conference. Our friend, Dr. Bannerjee was saying that because of the short dura- tion of courses, he could not go shopping. To arrange a 2 day conference, we have to make preparations for more than six months. I have to congratulate Dr. N.M. Samuel and his team from the Department of Experimental Medicine who made this conference successful, useful and informative. People come to a conference to listen but this type of conference involves equally informed participants. We purposely put it as a Round Table Conference. It was a participatory conference. I sincerely thank the participants for giving us your time. I thank the Government of Tamil Nadu, Dr. N.M. Samuel, Dr. Uma Dethan, the staff of the Department of Experimental Medicine and participants from all the medical colleges for giving such good support. The Proceedings have to be published and sent to each one present here for your suggestions. My personal desire is that we have to publish it in most of the Indian languages and should go to various states. The next International Conference on AIDS India will be in December 1999 and I would like to see all of you again.

Thank You.

CLOSING CEREMONY

Dr. N.M. Samuel
Organising Secretary

Revered Vice-Chancellor, dignitaries, ladies and gentlemen,

I thank all the participants for accepting our invitation . I am most grateful to you for being here and attending all the sessions. My special thanks to the President of the Conference Dr. Raja and to Dr. Ammann, the Conference Chair. Last year, Arthur came alone, this year he came with his wife and I hope he will bring his children next year. My thanks to the co-chairs Dr. Jacob John, Dr. Wendy Holmes, Dr Alka Deshpande and Dr. Uma Dethan. Some of you have come a long way, Dr. Keen, Dr. Fawzi. and Dr. Dax, thank you. We are hoping that a time would come when we could integrate all the laboratories in the State and have quality assurance programmes with the National Serology Reference Laboratory, where Dr. Liz Dax is the director. We look forward to working with you, Dr. Dax, and I hope it will benefit our country. I thank our co-sponsors, Glaxo Wellcome, the UNICEF and the Elizabeth Glaser Paediatric AIDS Foundation. Thanks to Mr. K.N. Chandrasekar who has been interacting with us for several months before this meeting as to how they could be a part of this meeting and I thank you on behalf of this University. I would be failing in my duty if I do not thank my own departmental staff who worked with me. I thank all the press persons and the TV for covering the programme. President Sir, ladies and gentlemen, we have met for the last 2 days. We renewed contacts, we made new contacts and some of us have met for the first time and made friendships. And I hope that these personal inter- actions will lead to scientific collaborations to achieve the main objective, that it is possible to reduce the perinatal mortality and paediatric AIDS burden of our country. And I hope that you will spread this message of hope to those affected and the infected.

POSTSCRIPT

As every one who participated in the conference seemed to agree, it was an active and stimulating conference. I believe the variety of participants, some responsible for policy making, some responsible for teaching, some others responsible for advising and assisting Mother to Child Transmission (MTCT) programmes on international levels, was one of the main reasons for the conference being such a success, and as the one who initiated the concept, planning and preparation of the conference, before it was handed over to the capable hands of Dr. Arthur Ammann the Conference Chair and his co-chairs. I was most gratified with the outcome of the Conference.

I apologize for mistakes you might find in this publication which is due to many factors like defective recording, the technical difficulties of transcribing and for authors not sending the manuscripts.

As the Proceedings go to the press, the PETRA study results show that the combination of AZT with 3TC offer additional benefits in reducing MTCT of HIV. We need to develop effective, efficient, and economical strategies to reduce MTCT in our country.

Before closing, I would like to offer my gratitude to all those who were willing to co-operate with me and my colleagues in the Department of Experimental Medicine and AIDS Resource Centre. Since the beginning of our work 6 years ago, several offered help and encouraged us, in particular Drs. Lalitha Kameshwaran, Rajan, Raja and Anandakannan - my heartfelt gratitude to them. Many thanks to our overseas friends who assisted and supported our efforts here in India - Drs. Jager, Kurimura, Saladin Osmanov, Helga Geiger, Amanda Murphy and Vinayak.

I hope the Proceedings will be a useful pointer for future undertakings to implement the effective strategies in the control of HIV/AIDS in India.

Dr. N.M. Samuel
Organising Secretary

APPENDIX

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CONFERENCE SECRETARIAT

Round Table Conference
Prevention of HIV Transmission from Mother to Infants-Strategies for India.
November 6th and 7th 1998

President	:	Dr. (Major) D. Raja Vice-Chancellor
Conference Chair	:	Dr. Arthur Ammann USA
Co-chairs	:	Dr. Alka Deshpande India Dr. T. Jacob John India Dr. Mark Weinberg Canada Dr. Wendy Holmes Australia Dr. P. Krishnamurthy India
Organising Secretary	:	Dr. N.M. Samuel Department of Experimental Medicine & AIDS Resource Centre The Tamil Nadu Dr. M.G.R. Medical University, 40 Anna Salai, Chennai (Madras), India Phone:+ 91 44 2354203 Fax:+ 91 44 2346750
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PROGRAMME

November 6th, 1998 Morning Session: 10.30 am -1.30 pm

Chairperson:	Dr. Arthur Ammann President of American Foundation For AIDS Research	Co-Chairs. 1. Dr. Uma Dethan Director of Medical Education, Government of Kerala, Trivandrum 2. Dr. Arthur Amman
10.30-10.50	The Changing Trends of HIV/AIDS Scenario in India	Dr. N.M. Samuel Dept. of Experimental Medicine and AIDS Resource Centre TN Dr. MGR Medical University Chennai
10.50-11.10	Pathogenesis and Prevention of Perinatal HIV Transmission:	Dr. Arthur Ammann President of American Foundation on AIDS Research, USA'
11.10-11.30	Review of Ongoing Trials for Prevention of Mother to Child Transmission of HIV	Dr. Dorothy Bray Senior Clinical Program, Head Glaxo Wellcome R&D. UK
11.30-11.50	Results of Modified ACTG076 Trial, Mumbai - The IHO-WADIA Model	Dr. R.H. Merchant Prof. of Paediatrics Belfor Clinic, Mumbai, India
11.50-12.00	Result of Observational Study at Chennai	Dr.S.Parameshwari Research Officer Dept. of Experimental Medicine and AIDS.Resource Centre TN Dr. MGR Medical University
12.00-12.20 p.m.	Results of Clinical Trials in Thailand	Dr. G. Forster Medical Director Roche, Thailand
12.20-12.40	Current Techniques Used in the Diagnosis of HIV infection in Infants and Relevance of Viral Load in Perinatal Transmission	Dr. Elizabeth Dax Director, National Serology Laboratory Australia
12.40-01.00	Towards formulation of a National Policy on Prevention of Perinatal Transmission of HIV	Dr.Jayaprakash Muliyil Professor, Dept. of Community Health CHAD, CMCH, Vellore
01.00-01.30	Discussion	
01.30-02.30	LUNCH	

November 6th, 1998 Afternoon Session: 2.30 - 4.30 p.m.

Chairperson:	Dr. T.Jacob John Emeritus Scientist, ICMR, CMC, Vellore	Co-chairs; 1. Dr. P. Krishnamoorthy Project Director, APAC, Chennai 2. Dr. Dorothy Bray Senior Clinical Program, Head Glaxo Wellcome, U.K.
2.30-2.45	Immunological Aspects of Perinatal HIV Transmission	Dr.Savitha Pahwa Chief, Dept. of Paediatrics, North Shore University Hospital, USA
2.45-3.00	Placebo Controlled Trials Scientifically Justified?	Dr. Thomas Cherian Prof. of Paediatrics, CMCH, Vellore, India
3.00-3.15	Breast Feeding Promotion in India in the Context of the HIV Epidemic	Dr.WendyHolmes Health Specialist, Macfarlane Centre Melbourne, Australia
3.15-3.30	Micronutrient Interventions Among HIV Infected Women and Children	Dr. Wafaie W. Fawzi Asst. Professor, Dept. of Nutrition, Harvard School of Public Health, USA
3.30-3.45	Results of PMPA in Reducing Perinatal Transmission	Dr. Koen K.A. Van Rompay Asst.Research Virologist, California Regional Primate Research Centre, USA
3.45-4.00	Testing and Counselling of Registered and Unregistered mothers	Dr. Suniti Solomon Director, YRG Care, Chennai
4.00-4.15	Ethics, Economics, Culture and Research	Dr. T. Jacob John Emeritus Scientist Indian Council of Medical Research, CMCH, Vellore
4.15-4.30	Community's Response in the Successful Implementation of an Intervention Strategy to Prevent Perinatal Transmission	Dr.Gilada Secretary General, Indian Health Organisation, Mumbai
4.30-5.30	Discussion	

November 7th, 1998 Morning Session: 9.00am - 12.00Noon

Group Discussion	*Cheairpersons*	
Group I Intervention Strategies for India	Dr. Alka Deshpande Prof. & HOD Medicine Mumbai	Dr.Shanmuga Priya DME at IOG, Chennai
Group II HIV testing and Counselling	Dr. Sheila Shyamprasad C.S.I. Rainy Hospital, Chennai	Dr. Gilada Secretary General, IHO Mumbai
Group III Community Participation in Planning and Implementation	Dr. Jayaprakash Muliyil Prof. Dept. of Community Health, CMC, Vellore	Dr. K.S. Bharucha Prof. HOD O & G Mumbai
Group IV Policy on Breast-feeding	Dr. Wendy Holmes Health Specialist Macfarlane Burnet Centre, Australia	Dr. P. Manorama Director CHES
Group V Effective and Safe Strategy (if available) to be Integrated into Public Health Structure-How?	Dr. T. Jacob John Emeritus Scientist, ICMC, CMC, Vellore	Dr. Sankaran (Retd.) Prof. of Medicine Chennai Medical College Chennai
Group VI Laboratory Services	Dr. Elizabeth Dax Director, National Serology Laboratory Australia	Dr. Dorothy Bray Senior Clinical Program, Head Glaxo Wellcome R & D U.K.
12.00 p.m. -1.00 p.m.	LUNCH	
12.00 p.m. -3.00 p.m.	Presentation of Reports	
3.00 p.m.	Closing ceremony &. Adjourn	

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